

EXHIBIT C

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. PTO-P-2018-0053]

2019 Revised Patent Subject Matter Eligibility Guidance

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Examination Guidance; Request for comments.

SUMMARY: The United States Patent and Trademark Office (USPTO) has prepared revised guidance (2019 Revised Patent Subject Matter Eligibility Guidance) for use by USPTO personnel in evaluating subject matter eligibility. The 2019 Revised Patent Subject Matter Eligibility Guidance revises the procedures for determining whether a patent claim or patent application claim is directed to a judicial exception (laws of nature, natural phenomena, and abstract ideas) under Step 2A of the USPTO's Subject Matter Eligibility Guidance in two ways. First, the 2019 Revised Patent Subject Matter Eligibility Guidance explains that abstract ideas can be grouped as, e.g., mathematical concepts, certain methods of organizing human activity, and mental processes. Second, this guidance explains that a patent claim or patent application claim that recites a judicial exception is not "directed to" the judicial exception if the judicial exception is integrated into a practical application of the judicial exception. A claim that recites a judicial exception, but is not integrated into a practical application, is directed to the judicial exception under Step 2A and must then be evaluated under Step 2B (inventive concept) to determine the subject matter eligibility of the claim. The USPTO is seeking public comment on its subject matter eligibility guidance, and particularly the 2019 Revised Patent Subject Matter Eligibility Guidance.

DATES:

Applicable Date: The 2019 Revised Patent Subject Matter Eligibility Guidance is effective on January 7, 2019. The 2019 Revised Patent Subject Matter Eligibility Guidance applies to all applications, and to all patents resulting from applications, filed before, on, or after January 7, 2019.

Comment Deadline Date: Written comments must be received on or before March 8, 2019.

ADDRESSES: Comments must be sent by electronic mail message over the internet addressed to: *Eligibility2019@uspto.gov*.

Electronic comments submitted in plain text are preferred, but also may be submitted in ADOBE® portable document format or MICROSOFT WORD® format. Comments not submitted electronically should be submitted on paper in a format that facilitates convenient digital scanning into ADOBE® portable document format. The comments will be available for viewing via the USPTO's internet website (<http://www.uspto.gov>). Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT: June E. Cohan, Senior Legal Advisor, at 571-272-7744 or Carolyn Kosowski, Senior Legal Advisor, at 571-272-7688, both with the Office of Patent Legal Administration.

SUPPLEMENTARY INFORMATION: Patent subject matter eligibility under 35 U.S.C. 101 has been the subject of much attention over the past decade. Recently, much of that attention has focused on how to apply the U.S. Supreme Court's framework for evaluating eligibility (often called the *Alice/Mayo* test).¹ Properly applying the *Alice/Mayo* test in a consistent manner has proven to be difficult, and has caused uncertainty in this area of the law. Among other things, it has become difficult in some cases for inventors, businesses, and other patent stakeholders to reliably and predictably determine what subject matter is patent-eligible. The legal uncertainty surrounding Section 101 poses unique

challenges for the USPTO, which must ensure that its more than 8500 patent examiners and administrative patent judges apply the *Alice/Mayo* test in a manner that produces reasonably consistent and predictable results across applications, art units and technology fields.

Since the *Alice/Mayo* test was announced and began to be extensively applied, the courts and the USPTO have tried to consistently distinguish between patent-eligible subject matter and subject matter falling within a judicial exception. Even so, patent stakeholders have expressed a need for more clarity and predictability in its application. In particular, stakeholders have expressed concern with the proper scope and application of the "abstract idea" exception. Some courts share these concerns, for example as demonstrated by several recent concurrences and dissents in the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") calling for changes in the application of Section 101 jurisprudence.² Many stakeholders, judges, inventors, and practitioners across the spectrum have argued that something needs to be done to increase clarity and consistency in how Section 101 is currently applied.

To address these and other concerns, the USPTO is revising its examination procedure with respect to the first step of the *Alice/Mayo* test³ (Step 2A of the USPTO's Subject Matter Eligibility Guidance as incorporated into the Manual of Patent Examining Procedure ("MPEP") 2106)⁴ by: (1) Providing groupings of subject matter that is considered an abstract idea; and (2) clarifying that a claim is not "directed to" a judicial exception if the judicial exception is integrated into a practical application of that exception.

² See, e.g., *Interval Licensing LLC, v. AOL, Inc.*, 896 F.3d 1335, 1348 (Fed. Cir. 2018) (Plager, J., concurring in part and dissenting in part); *Smart Sys. Innovations, LLC v. Chicago Transit Auth.*, 873 F.3d 1364, 1377 (Fed. Cir. 2017) (Linn, J., dissenting in part and concurring in part); *Berkheimer v. HP Inc.*, 890 F.3d 1369, 1376 (Fed. Cir. 2018) (Lourie, J., joined by Newman, J., concurring in denial of rehearing en banc).

³ The first step of the *Alice/Mayo* test is to determine whether the claims are "directed to" a judicial exception. *Alice*, 573 U.S. at 217 (citing *Mayo*, 566 U.S. at 77).

⁴ All references to the MPEP in the 2019 Revised Patent Subject Matter Eligibility Guidance are to the Ninth Edition, Revision 08-2017 (rev. Jan. 2018), unless otherwise indicated.

¹ *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217-18 (2014) (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012)).

Section I of this 2019 Revised Patent Subject Matter Eligibility Guidance explains that the judicial exceptions are for subject matter that has been identified as the “basic tools of scientific and technological work,”⁵ which includes “abstract ideas” such as mathematical concepts, certain methods of organizing human activity, and mental processes; as well as laws of nature and natural phenomena. Only when a claim recites a judicial exception does the claim require further analysis in order to determine its eligibility. The groupings of abstract ideas contained in this guidance enable USPTO personnel to more readily determine whether a claim recites subject matter that is an abstract idea.

Section II explains that the USPTO has set forth a revised procedure, rooted in Supreme Court caselaw, to determine whether a claim is “directed to” a judicial exception under the first step of the *Alice/Mayo* test (USPTO Step 2A).

Section III explains the revised procedure that will be applied by the USPTO. The procedure focuses on two aspects of Revised Step 2A: (1) Whether the claim recites a judicial exception; and (2) whether a recited judicial exception is integrated into a practical application. Only when a claim recites a judicial exception and fails to integrate the exception into a practical application, is the claim “directed to” a judicial exception, thereby triggering the need for further analysis pursuant to the second step of the *Alice/Mayo* test (USPTO Step 2B). Finally, if further analysis at Step 2B is needed (for example to determine whether the claim merely recites well-understood, routine, conventional activity), this 2019 Revised Patent Subject Matter Eligibility Guidance explains that the examiner or administrative patent judge will proceed in accordance with existing USPTO guidance as modified in April 2018.⁶

The USPTO is seeking public comment on its subject matter eligibility guidance, and particularly the 2019 Revised Patent Subject Matter Eligibility Guidance. The USPTO is determined to continue its mission to provide predictable and reliable patent rights in

accordance with this rapidly evolving area of the law. The USPTO’s ultimate goal is to draw distinctions between claims to principles in the abstract and claims that integrate those principles into a practical application. To that end, the USPTO may issue further guidance, or modify the current guidance, in the future based on its review of the comments received, further experience of the USPTO and its stakeholders, and additional judicial actions. Implementation of examination guidance on eligibility is an iterative process and may continue with periodic supplements. The USPTO invites the public to submit suggestions on eligibility-related topics to address in future guidance supplements as part of their comments on the USPTO’s subject matter eligibility guidance.

Impact on Examination Procedure and Prior Examination Guidance: This 2019 Revised Patent Subject Matter Eligibility Guidance supersedes MPEP 2106.04(II) (Eligibility Step 2A: Whether a Claim Is Directed to a Judicial Exception) to the extent it equates claims “reciting” a judicial exception with claims “directed to” a judicial exception, along with any other portion of the MPEP that conflicts with this guidance. A chart identifying portions of the MPEP that are affected by this guidance will be available for viewing via the USPTO’s internet website (<http://www.uspto.gov>). This 2019 Revised Patent Subject Matter Eligibility Guidance also supersedes all versions of the USPTO’s “Eligibility Quick Reference Sheet Identifying Abstract Ideas” (first issued in July 2015 and updated most recently in July 2018). Eligibility-related guidance issued prior to the Ninth Edition, R–08.2017, of the MPEP (published Jan. 2018) should not be relied upon. However, any claim considered patent eligible under prior guidance should be considered patent eligible under this guidance.

This guidance does not constitute substantive rulemaking and does not have the force and effect of law. The guidance sets out agency policy with respect to the USPTO’s interpretation of the subject matter eligibility requirements of 35 U.S.C. 101 in view of decisions by the Supreme Court and the Federal Circuit. The guidance was developed as a tool for internal USPTO management and does not create any right or benefit, substantive or procedural, enforceable by any party against the USPTO. Rejections will continue to be based upon the substantive law, and it is those rejections that are appealable to the Patent Trial and Appeal Board (PTAB) and the courts. All USPTO personnel

are, as a matter of internal agency management, expected to follow the guidance. Failure of USPTO personnel to follow the guidance, however, is not, in itself, a proper basis for either an appeal or a petition.

I. Groupings of Abstract Ideas

The Supreme Court has held that the patent eligibility statute, Section 101, contains an implicit exception for “[l]aws of nature, natural phenomena, and abstract ideas,” which are “the basic tools of scientific and technological work.”⁷ Yet, the Court has explained that “[a]t some level, all inventions embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,” and has cautioned “to tread carefully in construing this exclusionary principle lest it swallow all of patent law.”⁸

Since the *Alice* case, courts have been “compare[ing] claims at issue to those claims already found to be directed to an abstract idea in previous cases.”⁹ Likewise, the USPTO has issued guidance to the patent examining corps about Federal Circuit decisions applying the *Alice/Mayo* test, for instance describing the subject matter claimed in the patent in suit and noting whether or not certain subject matter has been identified as an abstract idea.¹⁰

⁷ *Alice Corp.*, 573 U.S. at 216 (internal citation and quotation marks omitted); *Mayo*, 566 U.S. at 71.

⁸ *Id.* (internal citation and quotation marks omitted).

⁹ See *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1334 (Fed. Cir. 2016); see also *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1294 (Fed. Cir. 2016) (“[T]he decisional mechanism courts now apply [to identify an abstract idea] is to examine earlier cases in which a similar or parallel descriptive nature can be seen—what prior cases were about, and which way they were decided.”).

¹⁰ See, e.g., 2014 Interim Guidance on Subject Matter Eligibility, 79 FR 74618, 74628–32 (Dec. 16, 2014) (discussing concepts identified as abstract ideas); July 2015 Update: Subject Matter Eligibility (Jul. 30, 2015), at 3–5, available at <https://www.uspto.gov/sites/default/files/documents/ieg-july-2015-update.pdf> (same); USPTO Memorandum of May 19, 2016, “Recent Subject Matter Eligibility Decisions (*Enfish, LLC v. Microsoft Corp.* and *TLI Communications LLC v. A.V. Automotive, LLC*),” at 2 (May 19, 2016), available at https://www.uspto.gov/sites/default/files/documents/ieg-may-2016_enfish_memo.pdf [hereinafter, “USPTO *Enfish* Memorandum”] (discussing the abstract idea in *TLI Communications LLC v. A.V. Automotive, LLC*, 823 F.3d 607 (Fed. Cir. 2016)); USPTO Memorandum of November 2, 2016, “Recent Subject Matter Eligibility Decisions,” at 2 (Nov. 2, 2016), available at <https://www.uspto.gov/sites/default/files/documents/McRo-Bascom-Memo.pdf> [hereinafter, “USPTO *McRo* Memorandum”] (discussing how the claims in *McRo, Inc. v. Bandai Namco Games America Inc.*, 837 F.3d 1299 (Fed. Cir. 2016), were directed to an improvement instead of an abstract idea); USPTO Memorandum of April 2, 2018, “Recent Subject Matter Eligibility Decisions” (Apr. 2, 2018), available at <https://www.uspto.gov/sites/default/files/documents/memo-recent-sme-ctdec-20180402.PDF> [hereinafter

Continued

⁵ *Mayo*, 566 U.S. at 71 (“Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work”) (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

⁶ USPTO Memorandum of April 19, 2018, “Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (*Berkheimer v. HP, Inc.*)” (Apr. 19, 2018), available at <https://www.uspto.gov/sites/default/files/documents/memo-berkheimer-20180419.PDF> [hereinafter “USPTO *Berkheimer* Memorandum”].

While that approach was effective soon after *Alice* was decided, it has since become impractical. The Federal Circuit has now issued numerous decisions identifying subject matter as abstract or non-abstract in the context of specific cases, and that number is continuously growing. In addition, similar subject matter has been described both as abstract and not abstract in different cases.¹¹ The growing body of precedent has become increasingly more difficult for examiners to apply in a predictable manner, and concerns have been raised that different examiners within and between technology centers may reach inconsistent results.

The USPTO, therefore, aims to clarify the analysis. In accordance with judicial precedent and in an effort to improve consistency and predictability, the 2019 Revised Patent Subject Matter Eligibility Guidance extracts and synthesizes key concepts identified by the courts as abstract ideas to explain that the abstract idea exception includes the following groupings of subject matter, when recited as such in a claim limitation(s) (that is, when recited on their own or per se):

“USPTO *Finjan* Memorandum”] (discussing how the claims in *Finjan Inc. v. Blue Coat Systems, Inc.*, 879 F.3d 1299 (Fed. Cir. 2018), and *Core Wireless Licensing, S.A.R.L. v. LG Electronics, Inc.*, 880 F.3d 1356 (Fed. Cir. 2018), were directed to improvements instead of abstract ideas); USPTO *Berkheimer* Memorandum at 2 (discussing the abstract idea in *Berkheimer*); MPEP 2106.04(a) (reviewing cases that did and did not identify abstract ideas).

¹¹ E.g., compare *TLI Commc'ns*, 823 F.3d at 611, with *Enfish*, 822 F.3d at 1335, and *Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253, 1258 (Fed. Cir. 2017). While computer operations such as “output of data analysis . . . can be abstract,” *Credit Acceptance Corp. v. Westlake Servs.*, 859 F.3d 1044, 1056 (Fed. Cir. 2017), “software-based innovations can [also] make ‘non-abstract improvements to computer technology’ and be deemed patent-eligible subject matter at step 1 [of the *Mayo/Alice* test],” *Finjan*, 879 F.3d at 1304 (quoting *Enfish*, 822 F.3d at 1335). Indeed, the Federal Circuit has held that “improvements in computer-related technology” and “claims directed to software” are not “inherently abstract.” *Enfish*, 822 F.3d at 1335; see also *Visual Memory*, 867 F.3d at 1258. These developments in the caselaw can create complications for the patent-examination process. For example, claims in one application could be deemed to be abstract, whereas slightly different claims directed to the same or similar subject matter could be determined to reflect a patent eligible “improvement.” Alternatively, claims in one application could be found to be abstract, whereas claims to the same or similar subject matter in another application, containing additional or different embodiments in the specification, could be deemed eligible as not directed to an abstract idea. In other words, the finding that the subject matter claimed in a prior patent was “abstract” as claimed may not determine whether similar subject matter in another application, claimed somewhat differently or supported by a different disclosure, is directed to an abstract idea and therefore patent ineligible.

(a) Mathematical concepts—mathematical relationships, mathematical formulas or equations, mathematical calculations;¹²

(b) Certain methods of organizing human activity—fundamental economic principles or practices (including hedging, insurance, mitigating risk); commercial or legal interactions (including agreements in the form of contracts; legal obligations; advertising, marketing or sales activities or behaviors; business relations); managing personal behavior or relationships or interactions between people (including social activities, teaching, and following rules or instructions);¹³ and

(c) Mental processes—concepts performed in the human mind¹⁴ (including an observation, evaluation, judgment, opinion).¹⁵

¹² *Bilski v. Kappos*, 561 U.S. 593, 611 (2010) (“The concept of hedging . . . reduced to a mathematical formula . . . is an unpatentable abstract idea[.]”); *Diamond v. Diehr*, 450 U.S. 175, 191 (1981) (“A mathematical formula as such is not accorded the protection of our patent laws”) (citing *Benson*, 409 U.S. 63); *Parker v. Flook*, 437 U.S. 584, 594 (1978) (“[T]he discovery of [a mathematical formula] cannot support a patent unless there is some other inventive concept in its application.”); *Benson*, 409 U.S. at 71–72 (concluding that permitting a patent on the claimed invention “would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself”); *Mackay Radio & Telegraph Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939) (“[A] scientific truth, or the mathematical expression of it, is not patentable invention[.]”); *SAP America, Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1163 (Fed. Cir. 2018) (holding that claims to a “series of mathematical calculations based on selected information” are directed to abstract ideas); *Digitex Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344, 1350 (Fed. Cir. 2014) (holding that claims to a “process of organizing information through mathematical correlations” are directed to an abstract idea); *Bancorp Servs., LLC v. Sun Life Assurance Co. of Can. (U.S.)*, 687 F.3d 1266, 1280 (Fed. Cir. 2012) (identifying the concept of “managing a stable value protected life insurance policy by performing calculations and manipulating the results” as an abstract idea).

¹³ *Alice*, 573 U.S. at 219–20 (concluding that use of a third party to mediate settlement risk is a “fundamental economic practice” and thus an abstract idea); *id.* (describing the concept of risk hedging identified as an abstract idea in *Bilski* as “a method of organizing human activity”); *Bilski*, 561 U.S. at 611–612 (concluding that hedging is a “fundamental economic practice” and therefore an abstract idea); *Bancorp*, 687 F.3d at 1280 (concluding that “managing a stable value protected life insurance policy by performing calculations and manipulating the results” is an abstract idea); *Inventor Holdings, LLC v. Bed Bath & Beyond, Inc.*, 876 F.3d 1372, 1378–79 (Fed. Cir. 2017) (holding that concept of “local processing of payments for remotely purchased goods” is a “fundamental economic practice, which *Alice* made clear is, without more, outside the patent system.”); *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362–63 (Fed. Cir. 2015) (concluding that claimed concept of “offer-based price optimization” is an abstract idea “similar to other ‘fundamental economic concepts’ found to be abstract ideas by the Supreme Court and this court”); *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350, 1355 (Fed. Cir. 2014) (holding that concept of “creating a contractual relationship—a ‘transaction performance guaranty’” is an abstract idea); *In re Comiskey*, 554 F.3d 967, 981 (Fed. Cir. 2009) (claims directed to “resolving a legal dispute between two parties by the decision of a human arbitrator” are ineligible);

Ultramercial, Inc. v. Hulu, LLC, 772 F.3d 709, 715 (Fed. Cir. 2014) (holding that claim “describe[ing] only the abstract idea of showing an advertisement before delivering free content” is patent ineligible); *In re Ferguson*, 558 F.3d 1359, 1364 (Fed. Cir. 2009) (holding methods “directed to organizing business or legal relationships in the structuring of a sales force (or marketing company)” to be ineligible); *Credit Acceptance*, 859 F.3d 1044 at 1054 (“The Board determined that the claims are directed to the abstract idea of ‘processing an application for financing a purchase.’ . . . We agree.”); *Interval Licensing*, 896 F.3d at 1344–45 (concluding that “[s]tanding alone, the act of providing someone an additional set of information without disrupting the ongoing provision of an initial set of information is an abstract idea,” observing that the district court “pointed to the nontechnical human activity of passing a note to a person who is in the middle of a meeting or conversation as further illustrating the basic, longstanding practice that is the focus of the [patent ineligible] claimed invention.”); *Voter Verified, Inc. v. Election Systems & Software, LLC*, 887 F.3d 1376, 1385 (Fed. Cir. 2018) (finding the concept of “voting, verifying the vote, and submitting the vote for tabulation,” a “fundamental activity” that humans have performed for hundreds of years, to be an abstract idea); *In re Smith*, 815 F.3d 816, 818 (Fed. Cir. 2016) (concluding that “[a]pplicants’ claims, directed to rules for conducting a wagering game” are abstract).

¹⁴ If a claim, under its broadest reasonable interpretation, covers performance in the mind but for the recitation of generic computer components, then it is still in the mental processes category unless the claim cannot practically be performed in the mind. See *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1318 (Fed. Cir. 2016) (“[W]ith the exception of generic computer-implemented steps, there is nothing in the claims themselves that foreclose them from being performed by a human, mentally or with pen and paper.”); *Mortg. Grader, Inc. v. First Choice Loan Servs. Inc.*, 811 F.3d 1314, 1324 (Fed. Cir. 2016) (holding that computer-implemented method for “anonymous loan shopping” was an abstract idea because it could be “performed by humans without a computer”); *Versata Dev. Grp. v. SAP Am., Inc.*, 793 F.3d 1306, 1335 (Fed. Cir. 2015) (“Courts have examined claims that required the use of a computer and still found that the underlying, patent-ineligible invention could be performed via pen and paper or in a person’s mind.”); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1375, 1372 (Fed. Cir. 2011) (holding that the incidental use of “computer” or “computer readable medium” does not make a claim otherwise directed to process that “can be performed in the human mind, or by a human using a pen and paper” patent eligible); *id.* at 1376 (distinguishing *Research Corp. Techs. v. Microsoft Corp.*, 627 F.3d 859 (Fed. Cir. 2010), and *SIRF Tech., Inc. v. Int’l Trade Comm’n*, 601 F.3d 1319 (Fed. Cir. 2010), as directed to inventions that “could not, as a practical matter, be performed entirely in a human’s mind”). Likewise, performance of a claim limitation using generic computer components does not necessarily preclude the claim limitation from being in the mathematical concepts grouping. *Benson*, 409 U.S. at 67, or the certain methods of organizing human activity grouping. *Alice*, 573 U.S. at 219–20.

¹⁵ *Mayo*, 566 U.S. at 71 (“[M]ental processes[] and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”) (quoting *Benson*, 409 U.S. at 67)); *Flook*, 437 U.S. at 589 (same); *Benson*, 409 U.S. at 67, 65 (noting that the claimed “conversion of [binary-coded decimal] numerals to pure binary numerals can be done mentally,” i.e., “as a person

Claims that do not recite matter that falls within these enumerated groupings of abstract ideas should not be treated as reciting abstract ideas, except as follows: In the rare circumstance in which a USPTO employee believes a claim limitation that does not fall within the enumerated groupings of abstract ideas should nonetheless be treated as reciting an abstract idea, the procedure described in Section III.C for analyzing the claim should be followed.

II. “Directed To” a Judicial Exception

The Supreme Court has long distinguished between principles themselves (which are not patent eligible) and the integration of those principles into practical applications (which are patent eligible).¹⁶ Similarly,

would do it by head and hand.”); *Synopsis, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1139, (Fed. Cir. 2016) (holding that claims to the mental process of “translating a functional description of a logic circuit into a hardware component description of the logic circuit” are directed to an abstract idea, because the claims “read on an individual performing the claimed steps mentally or with pencil and paper”); *Mortg. Grader*, 811 F.3d, at 1324 (concluding that concept of “anonymous loan shopping” is an abstract idea because it could be “performed by humans without a computer”); *In re BRCA1 & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 763 (Fed. Cir. 2014) (concluding that concept of “comparing BRCA sequences and determining the existence of alterations” is an “abstract mental process”); *In re Brown*, 645 F. App’x. 1014, 1017 (Fed. Cir. 2016) (non-precedential) (claim limitations “encompass the mere idea of applying different known hair styles to balance one’s head. Identifying head shape and applying hair designs accordingly is an abstract idea capable, as the Board notes, of being performed entirely in one’s mind”).

¹⁶ See, e.g., *Alice*, 573 U.S. at 217 (explaining that “in applying the § 101 exception, we must distinguish between patents that claim the ‘building[ing] block[s]’ of human ingenuity and those that integrate the building blocks into something more” (quoting *Mayo*, 566 U.S. at 89) and stating that *Mayo* “set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts”); *Mayo*, 566 U.S. at 80, 84 (noting that the Court in *Diehr* found “the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole,” but the Court in *Benson* “held that simply implementing a mathematical principle on a physical machine, namely a computer, was not a patentable application of that principle”); *Bilski*, 561 U.S. at 611 (“*Diehr* explained that while an abstract idea, law of nature, or mathematical formula could not be patented, ‘an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.’” (quoting *Diehr*, 450 U.S. at 187) (emphasis in original)); *Diehr*, 450 U.S. at 187, 192 n.14 (explaining that the process in *Flook* was ineligible not because it contained a mathematical formula, but because it did not provide an application of the formula); *Mackay Radio*, 306 U.S. at 94 (“While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”); *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852) (“The elements of the [natural phenomena] exist; the

in a growing body of decisions, the Federal Circuit has distinguished between claims that are “directed to” a judicial exception (which require further analysis to determine their eligibility) and those that are not (which are therefore patent eligible).¹⁷ For example, an improvement in the functioning of a computer or other technology or technological field may render a claim patent eligible at step one of the *Alice/Mayo* test even if it recites an abstract idea, law of nature, or natural phenomenon.¹⁸ Moreover, recent Federal Circuit jurisprudence has indicated that eligible subject matter can often be identified either at the first or the second step of the *Alice/Mayo* test.¹⁹

invention is not in discovering them, but in applying them to useful objects.”).

¹⁷ See, e.g., MPEP 2106.06(b) (summarizing *Enfish*, *McRO*, and other cases that were eligible as improvements to technology or computer functionality instead of abstract ideas); USPTO *Finjan* Memorandum (discussing *Finjan*, and *Core Wireless*); USPTO Memorandum of June 7, 2018, “Recent Subject Matter Eligibility Decision: *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*,” available at <https://www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.PDF> [hereinafter “USPTO *Vanda* Memorandum”]; *BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1352 (Fed. Cir. 2016) (concluding that claims could be eligible if ordered combination of limitations “transform the abstract idea . . . into a particular, practical application of that abstract idea.”); *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1056–57 (Fed. Cir. 1992) (“As the jurisprudence developed, inventions that were implemented by the mathematically-directed performance of computers were viewed in the context of the practical application to which the computer-generated data were put.”); *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1315 (Fed. Cir. 2013) (Moore, J., joined by Rader, C.J., and Linn and O’Malley, JJ., dissenting in part) (“The key question is thus whether a claim recites a sufficiently concrete and practical application of an abstract idea to qualify as patent-eligible.”), *aff’d*, 573 U.S. 208 (2014).

¹⁸ See, e.g., *McRO*, 837 F.3d at 1316; *Enfish*, 822 F.3d at 1336; *Core Wireless*, 880 F.3d at 1362.

¹⁹ See, e.g., *Vanda Pharm. Inc. v. West-Ward Pharm. Int’l Ltd.*, 887 F.3d 1117, 1134 (Fed. Cir. 2018) (“If the claims are not directed to a patent ineligible concept at step one, we need not address step two of the inquiry.”); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016) (holding that claimed invention is patent eligible because it is not directed to a patent-ineligible concept under step one or is an inventive application of the patent-ineligible concept under step two); *Enfish*, 822 F.3d at 1339 (noting that eligibility determination can be reached either because claims not directed to an abstract idea under step one or recite a concrete improvement under step two); *McRO*, 837 F.3d at 1313 (recognizing that the “court must look to the claims as an ordered combination” in determining patentability “[w]hether at step one or step two of the *Alice* test”); *Amdocs*, 841 F.3d at 1294 (observing that recent cases “suggest that there is considerable overlap between step one and step two, and in some situations [the inventive concept] analysis could be accomplished without going beyond step one”). See also *Ancora Techs. v. HTC Am.*, 908 F.3d 1343, 1349 (Fed. Cir. 2018) (noting, in accord with the “recognition of overlaps between

These revised patent examination procedures are designed to more accurately and consistently identify claims that recite a practical application of a judicial exception (and thus are not “directed to” a judicial exception), thereby increasing predictability and consistency in the patent eligibility analysis. This analysis is performed at USPTO Step 2A, and incorporates certain considerations that have been applied by the courts at step one and at step two of the *Alice/Mayo* framework, given the recognized overlap in the steps depending on the facts of any given case.

In accordance with judicial precedent, and to increase consistency in examination practice, the 2019 Revised Patent Subject Matter Eligibility Guidance sets forth a procedure to determine whether a claim is “directed to” a judicial exception under USPTO Step 2A. Under the procedure, if a claim recites a judicial exception (a law of nature, a natural phenomenon, or an abstract idea as grouped in Section I, above), it must then be analyzed to determine whether the recited judicial exception is integrated into a practical application of that exception. A claim is not “directed to” a judicial exception, and thus is patent eligible, if the claim as a whole integrates the recited judicial exception into a practical application of that exception. A claim that integrates a judicial exception into a practical application will apply, rely on, or use the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception.

III. Instructions for Applying Revised Step 2A During Examination

Examiners should determine whether a claim satisfies the criteria for subject matter eligibility by evaluating the claim in accordance with the criteria discussed in MPEP 2106, *i.e.*, whether the claim is to a statutory category (Step 1) and the *Alice/Mayo* test for judicial exceptions (Steps 2A and 2B). The procedure set forth herein (referred to as “revised Step 2A”) changes how examiners should apply the first step of the *Alice/Mayo* test, which determines whether a claim is “directed to” a judicial exception.

As before, Step 1 of the USPTO’s eligibility analysis entails considering whether the claimed subject matter falls within the four statutory categories of

some step one and step two considerations,” that its conclusion of eligibility at step one is “indirectly reinforced by some of [its] prior holdings under step two”).

patentable subject matter identified by 35 U.S.C. 101: Process, machine, manufacture, or composition of matter. The 2019 Revised Patent Subject Matter Eligibility Guidance does not change Step 1 or the streamlined analysis, which are discussed in MPEP 2106.03 and 2106.06, respectively. Examiners may continue to use a streamlined analysis (Pathway A) when the patent eligibility of a claim is self-evident.

Step 2A of the 2019 Revised Patent Subject Matter Eligibility Guidance is a two-prong inquiry. In Prong One, examiners evaluate whether the claim recites a judicial exception.²⁰ This prong is similar to procedures in prior guidance except that when determining if a claim recites an abstract idea, examiners now refer to the subject matter groupings of abstract ideas in Section I instead of comparing the claimed concept to the USPTO's prior "Eligibility Quick Reference Sheet Identifying Abstract Ideas."

- If the claim recites a judicial exception (*i.e.*, an abstract idea enumerated in Section I of the 2019 Revised Patent Subject Matter Eligibility Guidance, a law of nature, or a natural phenomenon), the claim requires further analysis in Prong Two.

- If the claim does not recite a judicial exception (a law of nature, natural phenomenon, or subject matter within the enumerated groupings of abstract ideas in Section I), then the claim is eligible at Prong One of revised Step 2A. This concludes the eligibility analysis, except in the rare circumstance described below.²¹

- In the rare circumstance in which an examiner believes a claim limitation that does not fall within the enumerated groupings of abstract ideas should nonetheless be treated as reciting an abstract idea, the procedure described in Section III.C for analyzing the claim should be followed.

In Prong Two, examiners evaluate whether the claim recites additional elements that integrate the exception into a practical application of that

exception. This prong adds a more detailed eligibility analysis to step one of the *Alice/Mayo* test (USPTO Step 2A) than was required under prior guidance.

- If the recited exception is integrated into a practical application of the exception, then the claim is eligible at Prong Two of revised Step 2A. This concludes the eligibility analysis.

- If, however, the additional elements do not integrate the exception into a practical application, then the claim is directed to the recited judicial exception, and requires further analysis under Step 2B (where it may still be eligible if it amounts to an "inventive concept").²²

The following discussion provides additional detail on this revised procedure.

A. Revised Step 2A

1. Prong One: Evaluate Whether the Claim Recites a Judicial Exception

In Prong One, examiners should evaluate whether the claim recites a judicial exception, *i.e.*, an abstract idea, a law of nature, or a natural phenomenon. If the claim does not recite a judicial exception, it is not directed to a judicial exception (Step 2A: NO) and is eligible. This concludes the eligibility analysis. If the claim does recite a judicial exception, then it requires further analysis in Prong Two of Revised Step 2A to determine whether it is directed to the recited exception, as explained in Section III.A.2 of the 2019 Revised Patent Subject Matter Eligibility Guidance.

For abstract ideas, Prong One represents a change as compared to prior guidance. To determine whether a claim recites an abstract idea in Prong One, examiners are now to: (a) Identify the specific limitation(s) in the claim under examination (individually or in combination) that the examiner believes recites an abstract idea; and (b) determine whether the identified limitation(s) falls within the subject matter groupings of abstract ideas enumerated in Section I of the 2019 Revised Patent Subject Matter Eligibility Guidance. If the identified limitation(s) falls within the subject matter groupings of abstract ideas enumerated in Section I, analysis should proceed to Prong Two in order to evaluate whether the claim integrates the abstract idea into a

practical application. When evaluating Prong One, examiners are no longer to use the USPTO's "Eligibility Quick Reference Sheet Identifying Abstract Ideas," which has been superseded by this document.

In the rare circumstance in which an examiner believes a claim limitation that does not fall within the enumerated groupings of abstract ideas should nonetheless be treated as reciting an abstract idea, the procedure described in Section III.C for analyzing the claim should be followed.

For laws of nature and natural phenomena, Prong One does not represent a change. Examiners should continue to follow existing guidance to identify whether a claim recites one of these exceptions,²³ and if it does, proceed to Prong Two of the 2019 Revised Patent Subject Matter Eligibility Guidance in order to evaluate whether the claim integrates the law of nature or natural phenomenon into a practical application.

2. Prong Two: If the Claim Recites a Judicial Exception, Evaluate Whether the Judicial Exception Is Integrated Into a Practical Application

In Prong Two, examiners should evaluate whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. A claim that integrates a judicial exception into a practical application will apply, rely on, or use the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception. When the exception is so integrated, then the claim is not directed to a judicial exception (Step 2A: NO) and is eligible. This concludes the eligibility analysis. If the additional elements do not integrate the exception into a practical application, then the claim is directed to the judicial exception (Step 2A: YES), and requires further analysis under Step 2B (where it may still be eligible if it amounts to an inventive concept), as explained in Section III.B of the 2019 Revised Patent Subject Matter Eligibility Guidance.

Prong Two represents a change from prior guidance. The analysis under Prong Two is the same for all claims reciting a judicial exception, whether the exception is an abstract idea, a law of nature, or a natural phenomenon.

Examiners evaluate integration into a practical application by: (a) Identifying whether there are any additional elements recited in the claim beyond

²⁰ This notice does not change the type of claim limitations that are considered to recite a law of nature or natural phenomenon. For more information about laws of nature and natural phenomena, including products of nature, see MPEP 2106.04(b) and (c).

²¹ Even if a claim is determined to be patent eligible under section 101, this or any other step of the eligibility analysis does not end the inquiry. The claims must also satisfy the other conditions and requirements for patentability, for example, under section 102 (novelty), 103 (nonobviousness), or 112 (enablement, written description, definiteness). *Bilski*, 561 U.S. at 602. Examiners should take care not to confuse or intermingle patentability requirements of these separate sections with patent eligibility analysis under section 101.

²² See, e.g., *Amdocs*, 841 F.3d at 1300, 1303; *BASCOM*, 827 F.3d at 1349–52; *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1257–59 (Fed. Cir. 2014); USPTO *Berkheimer* Memorandum; see also *Rapid Litig.*, 827 F.3d at 1050 (holding that claimed invention is patent eligible because it is not directed to a patent-ineligible concept under step one or is an inventive application of the patent-ineligible concept under step two).

²³ See MPEP 2106.04(b)–(c).

the judicial exception(s); and (b) evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application, using one or more of the considerations laid out by the Supreme Court and the Federal Circuit, for example those listed below. While some of the considerations listed below were discussed in prior guidance in the context of Step 2B, evaluating them in revised Step 2A promotes early and efficient resolution of patent eligibility, and increases certainty and reliability. Examiners should note, however, that revised Step 2A specifically excludes consideration of whether the additional elements represent well-understood, routine, conventional activity. Instead, analysis of well-understood, routine, conventional activity is done in Step 2B. Accordingly, in revised Step 2A examiners should ensure that they give weight to all additional elements, whether or not they are conventional, when evaluating whether a judicial exception has been integrated into a practical application.

In the context of revised Step 2A, the following exemplary considerations are indicative that an additional element (or combination of elements)²⁴ may have integrated the exception into a practical application:

- An additional element reflects an improvement in the functioning of a computer, or an improvement to other technology or technical field;²⁵
- an additional element that applies or uses a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition;²⁶

²⁴ USPTO guidance uses the term “additional elements” to refer to claim features, limitations, and/or steps that are recited in the claim beyond the identified judicial exception. Again, whether an additional element or combination of elements integrate the exception into a practical application should be evaluated on the claim as a whole.

²⁵ For example, a modification of internet hyperlink protocol to dynamically produce a dual-source hybrid web page. See MPEP 2106.05(a) for more information concerning improvements in the functioning of a computer or to any other technology or technical field, including a discussion of the exemplar provided herein, which is based on *DDR Holdings*, 773 F.3d at 1258–59. See also USPTO *Finjan* Memorandum (discussing *Finjan* and *Core Wireless*).

²⁶ For example, an immunization step that integrates an abstract idea into a specific process of immunizing that lowers the risk that immunized patients will later develop chronic immune-mediated diseases. See, e.g., *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066–68 (Fed. Cir. 2011). See also *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1135 (Fed. Cir. 2018) (holding claims to the practical application of the natural relationships between iloperidone, CYP2D6 metabolism, and QTc prolongation to treat schizophrenia, not merely the recognition of those relationships, to be patent

- an additional element implements a judicial exception with, or uses a judicial exception in conjunction with, a particular machine or manufacture that is integral to the claim;²⁷
- an additional element effects a transformation or reduction of a particular article to a different state or thing;²⁸ and
- an additional element applies or uses the judicial exception in some other meaningful way beyond generally linking the use of the judicial exception to a particular technological environment, such that the claim as a whole is more than a drafting effort designed to monopolize the exception.²⁹

This is not an exclusive list, and there may be other examples of integrating the exception into a practical application. The courts have also identified examples in which a judicial exception has not been integrated into a practical application:

- An additional element merely recites the words “apply it” (or an equivalent) with the judicial exception, or merely includes instructions to implement an abstract idea on a computer, or merely uses a computer as a tool to perform an abstract idea;³⁰

eligible at *Mayo/Alice* step 1 (USPTO Step 2A)), and USPTO *Vanda* Memorandum (discussing *Vanda*).

²⁷ For example, a Fourdrinier machine (which is understood in the art to have a specific structure comprising a headbox, a paper-making wire, and a series of rolls) that is arranged in a particular way that uses gravity to optimize the speed of the machine while maintaining quality of the formed paper web. See MPEP 2106.05(b) for more information concerning use of a judicial exception with, or in conjunction with, a particular machine or manufacture, including a discussion of the exemplar provided herein, which is based on *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 64–65 (1923).

²⁸ For example, a process that transforms raw, uncured synthetic rubber into precision-molded synthetic rubber products by using a mathematical formula to control operation of the mold. See MPEP 2106.05(c) for more information concerning transformation or reduction of a particular article to a different state or thing, including a discussion of the exemplar provided herein, which is based on *Diehr*, 450 U.S. at 184.

²⁹ For example, a combination of steps including installing rubber in a press, closing the mold, constantly measuring the temperature in the mold, and automatically opening the press at the proper time, all of which together meaningfully limited the use of a mathematical equation to a practical application of molding rubber products. See MPEP 2106.05(e) for more information on this consideration, including a discussion of the exemplar provided herein, which is based on *Diehr*, 450 U.S. at 184, 187. See also USPTO *Finjan* Memorandum (discussing *Finjan* and *Core Wireless*).

³⁰ For example, a limitation indicating that a particular function such as creating and maintaining electronic records is performed by a computer, without specifying how. See MPEP 2106.05(f) for more information concerning mere instructions to apply a judicial exception, including a discussion of the exemplar provided herein, which is based on *Alice*, 573 U.S. at 222–26. See

- an additional element adds insignificant extra-solution activity to the judicial exception;³¹ and
- an additional element does no more than generally link the use of a judicial exception to a particular technological environment or field of use.³²

It is critical that examiners consider the claim as a whole when evaluating whether the judicial exception is meaningfully limited by integration into a practical application of the exception. Some elements may be enough on their own to meaningfully limit an exception, but other times it is the combination of elements that provide the practical application. When evaluating whether an element (or combination of elements) integrates an exception into a practical application, examiners should give careful consideration to both the element and how it is used or arranged in the claim as a whole. Because revised Step 2A does not evaluate whether an additional element is well-understood, routine, conventional activity, examiners are reminded that a claim that includes conventional elements may still integrate an exception into a practical application, thereby satisfying the subject matter eligibility requirement of Section 101.³³

also *Benson*, 409 U.S. 63 (holding that merely implementing a mathematical principle on a general purpose computer is a patent ineligible abstract idea); *Credit Acceptance Corp. v. Westlake Services*, 859 F.3d 1044 (Fed. Cir. 2017) (using a computer as a tool to process an application for financing a purchase).

³¹ For example, a mere data gathering such as a step of obtaining information about credit card transactions so that the information can be analyzed in order to detect whether the transactions were fraudulent. See MPEP 2106.05(g) for more information concerning insignificant extra-solution activity, including a discussion of the exemplar provided herein, which is based on *CyberSource*, 654 F.3d at 1375. See also *Mayo*, 566 U.S. at 79 (concluding that additional element of measuring metabolites of a drug administered to a patient was insignificant extra-solution activity, which was insufficient to confer patent eligibility); *Flook*, 437 U.S. at 590 (step of adjusting an alarm limit based on the output of a mathematical formula was “post-solution activity” and did not render method patent eligible).

³² For example, a claim describing how the abstract idea of hedging could be used in the commodities and energy markets, or a claim limiting the use of a mathematical formula to the petrochemical and oil-refining fields. See MPEP 2106.05(h) concerning generally linking use of a judicial exception to a particular technological environment or field of use, including a discussion of the exemplars provided herein, which are based on *Bilski*, 561 U.S. at 612, and *Flook*, 437 U.S. at 588–90. Thus, the mere application of an abstract method of organizing human activity in a particular field is not sufficient to integrate the judicial exception into a practical application.

³³ Of course, such claims must also satisfy the other conditions and requirements of patentability, for example, under section 102 (novelty), 103 (nonobviousness), and 112 (enablement, written description, definiteness). *Bilski*, 561 U.S. at 602.

B. Step 2B: If the Claim Is Directed to a Judicial Exception, Evaluate Whether the Claim Provides an Inventive Concept

It is possible that a claim that does not “integrate” a recited judicial exception is nonetheless patent eligible. For example the claim may recite additional elements that render the claim patent eligible even though a judicial exception is recited in a separate claim element.³⁴ Along these lines, the Federal Circuit has held claims eligible at the second step of the *Alice/Mayo* test (USPTO Step 2B) because the additional elements recited in the claims provided “significantly more” than the recited judicial exception (e.g., because the additional elements were unconventional in combination).³⁵ Therefore, if a claim has been determined to be directed to a judicial exception under revised Step 2A, examiners should then evaluate the additional elements individually and in combination under Step 2B to determine whether they provide an inventive concept (i.e., whether the additional elements amount to significantly more than the exception itself). If the examiner determines that the element (or combination of elements) amounts to significantly more than the exception itself (Step 2B: YES), the claim is eligible, thereby concluding the eligibility analysis. If the examiner determines that the element and combination of elements does not amount to significantly more than the exception itself, the claim is ineligible (Step 2B: NO) and the examiner should reject the claim for lack of subject matter eligibility.

While many considerations in Step 2A need not be reevaluated in Step 2B, examiners should continue to consider in Step 2B whether an additional element or combination of elements:

- Adds a specific limitation or combination of limitations that are not well-understood, routine, conventional activity in the field, which is indicative that an inventive concept may be present; or
- simply appends well-understood, routine, conventional activities previously known to the industry,

specified at a high level of generality, to the judicial exception, which is indicative that an inventive concept may not be present.³⁶

For this reason, if an examiner had previously concluded under revised Step 2A that, e.g., an additional element was insignificant extra-solution activity, they should reevaluate that conclusion in Step 2B. If such reevaluation indicates that the element is unconventional or otherwise more than what is well-understood, routine, conventional activity in the field, this finding may indicate that an inventive concept is present and that the claim is thus eligible.³⁷ For example, when evaluating a claim reciting an abstract idea such as a mathematical equation and a series of data gathering steps that collect a necessary input for the equation, an examiner might consider the data gathering steps to be insignificant extra-solution activity in revised Step 2A, and therefore find that the judicial exception is not integrated into a practical application.³⁸ However, when the examiner reconsiders the data gathering steps in Step 2B, the examiner could determine that the combination of steps gather data in an unconventional way and therefore include an “inventive concept,” rendering the claim eligible at Step 2B.³⁹ Likewise, a claim that does

not meaningfully integrate a judicial exception into a practical application of the exception sufficient to pass muster at Step 2A, may nonetheless include additional subject matter that is unconventional and thus an “inventive concept” at Step 2B.⁴⁰

C. Treating a Claim Limitation That Does Not Fall Within the Enumerated Groupings of Abstract Ideas as Reciting an Abstract Idea

In the rare circumstance in which an examiner believes a claim limitation that does not fall within the enumerated groupings of abstract ideas should

966 (Fed. Cir. 2018) (holding claimed body temperature detector to be eligible because: “Here, the patent is directed to the measurement of a natural phenomenon (core body temperature). Even if the concept of such measurement is directed to a natural phenomenon and is abstract at step one, the measurement method here was not conventional, routine, and well-understood. Following years and millions of dollars of testing and development, the inventor determined for the first time the coefficient representing the relationship between temporal-arterial temperature and core body temperature and incorporated that discovery into an unconventional method of temperature measurement.”).

⁴⁰ Compare *Berkheimer*, 881 F.3d at 1370 (holding independent claim 1 to be ineligible at *Alice* step 2: “The[] conventional limitations of claim 1, combined with limitations of analyzing and comparing data and reconciling differences between the data, fail to transform the abstract idea into a patent-eligible invention. The limitations amount to no more than performing the abstract idea of parsing and comparing data with conventional computer components”) (internal quotation marks and citation omitted); *with id.* (concluding that dependent claims 4–7 may be eligible: “Claims 4–7, in contrast, contain limitations directed to the arguably unconventional inventive concept described in the specification. Claim 4 recites ‘storing a reconciled object structure in the archive without substantial redundancy.’ The specification states that storing object structures in the archive without substantial redundancy improves system operating efficiency and reduces storage costs. It also states that known asset management systems did not archive documents in this manner. Claim 5 depends on claim 4 and further recites ‘selectively editing an object structure, linked to other structures to thereby effect a one-to-many change in a plurality of archived items.’ The specification states one-to-many editing substantially reduces effort needed to update files because a single edit can update every document in the archive linked to that object structure. This one-to-many functionality is more than ‘editing data in a straightforward copy-and-paste fashion,’ as characterized by the district court. According to the specification, conventional digital asset management systems cannot perform one-to-many editing because they store documents with numerous instances of redundant elements, rather than eliminate redundancies through the storage of linked object structures. Claims 6–7 depend from claim 5 and accordingly contain the same limitations. These claims recite a specific method of archiving that, according to the specification, provides benefits that improve computer functionality. . . . [T]here is at least a genuine issue of material fact in light of the specification regarding whether claims 4–7 archive documents in an inventive manner that improves these aspects of the disclosed archival system.”) (internal quotation marks and citations omitted).

³⁶ In accordance with existing guidance, an examiner’s conclusion that an additional element (or combination of elements) is well understood, routine, conventional activity must be supported with a factual determination. For more information concerning evaluation of well-understood, routine, conventional activity, see MPEP 2106.05(d), as modified by the USPTO *Berkheimer* Memorandum.

³⁷ *Mayo*, 566 U.S. at 82 (“[S]imply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.”); *but see id.* at 85 (“[T]he claimed process included not only a law of nature but also several unconventional steps (such as inserting the receptacle, applying heat to the receptacle externally, and blowing the air into the furnace) that confined the claims to a particular, useful application of the principle.” (discussing the old English case, *Neilson v. Harford*, Webster’s Patent Cases 295 (1841))).

³⁸ See *supra* note 34; see also *OIP Techs.*, 788 F.3d at 1363 (finding that gathering statistics generated based on customer testing for input to a pricing calculation “fail[s] to ‘transform’ the claimed abstract idea into a patent-eligible invention”).

³⁹ Compare *Flook*, 437 U.S. at 585–86 (holding claimed method of updating alarm limits to be ineligible because: “In essence, the method consists of three steps: an initial step which merely measures the present value of the process variable (e.g., the temperature); an intermediate step which uses an algorithm to calculate an updated alarm-limit value; and a final step in which the actual alarm limit is adjusted to the updated value. The only difference between the conventional methods of changing alarm limits and that described in respondent’s application rests in the second step—the mathematical algorithm or formula.”); *with Exergen Corp. v. Kaz USA, Inc.*, 725 F. App’x 959,

³⁴ See, e.g., *Diehr*, 450 U.S. at 187 (“Our earlier opinions lend support to our present conclusion that a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer.”); *id.* at 185 (“Our conclusion regarding respondents’ claims is not altered by the fact that in several steps of the process a mathematical equation and a programmed digital computer are used.”).

³⁵ See, e.g., *Amdocs*, 841 F.3d at 1300, 1303; *BASCOM*, 827 F.3d at 1349–52; *DDR Holdings*, 773 F.3d at 1257–59.

nonetheless be treated as reciting an abstract idea (“tentative abstract idea”), the examiner should evaluate whether the claim as a whole integrates the recited tentative abstract idea into a practical application as explained in Section III.A.2. If the claim as a whole integrates the recited tentative abstract idea into a practical application, the claim is not directed to a judicial exception (Step 2A: NO) and is eligible (thus concluding the eligibility analysis). If the claim as a whole does not integrate the recited tentative abstract idea into a practical application, then the examiner should evaluate the additional elements individually and in combination to determine whether they provide an inventive concept as explained in Section III.B. If an additional element or combination of additional elements provides an inventive concept as explained in Section III.B (Step 2B: YES), the claim is eligible (thus concluding the eligibility analysis). If the additional element or combination of additional elements does not provide an inventive concept as explained in Section III.B (Step 2B: NO), the examiner should bring the application to the attention of the Technology Center Director. Any rejection in which a claim limitation, which does not fall within the enumerated abstract ideas (tentative abstract idea), is nonetheless treated as reciting an abstract idea must be approved by the Technology Center Director (which approval will be indicated in the file record of the application), and must provide a justification⁴¹ for why such claim limitation is being treated as reciting an abstract idea.⁴²

D. Compact Prosecution

Regardless of whether a rejection under 35 U.S.C. 101 is made, a complete examination should be made for every claim under each of the other patentability requirements: 35 U.S.C. 102, 103, 112, and 101 (utility, inventorship and double patenting) and non-statutory double patenting.⁴³ Compact prosecution, however, does not mandate that the patentability

requirements be analyzed in any particular order.

Dated: December 20, 2018.

Andrei Iancu,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2018–28282 Filed 1–4–19; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. PTO–P–2018–0059]

Examining Computer-Implemented Functional Claim Limitations for Compliance With 35 U.S.C. 112

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Examination guidance; request for comments.

SUMMARY: This guidance will assist United States Patent and Trademark Office (USPTO) personnel in the examination of claims in patent applications that contain functional language, particularly patent applications where functional language is used to claim computer-implemented inventions. Part I of this guidance addresses issues related to the examination of computer-implemented functional claims having means-plus-function limitations. Part II of this guidance addresses written description and enablement issues related to the examination of computer-implemented functional claims that recite only the idea of a solution or outcome to a problem but fail to recite details of how the solution or outcome is accomplished.

DATES:

Applicable Date: The Computer-Implemented Functional Claim Limitations Guidance is effective on January 7, 2019. The Computer-Implemented Functional Claim Limitations Guidance applies to all applications, and to all patents resulting from applications, filed before, on or after January 7, 2019.

Comment Deadline Date: Written comments must be received on or before March 8, 2019.

ADDRESSES: Comments must be sent by electronic mail message over the internet addressed to:

112Guidance2019@uspto.gov.

Electronic comments submitted in plain text are preferred, but also may be submitted in ADOBE® portable document format or MICROSOFT

WORD® format. Comments not submitted electronically should be submitted on paper in a format that facilitates convenient digital scanning into ADOBE® portable document format. The comments will be available for viewing via the USPTO's internet website (<http://www.uspto.gov>). Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT:

Nicole D. Haines, Senior Legal Advisor, at 571–272–7717 or Jeffrey R. West, Senior Legal Advisor, at 571–272–2226, both with the Office of Patent Legal Administration.

SUPPLEMENTARY INFORMATION: The patent examination process must ensure that: (1) The claims of an application have proper written description and enablement support under 35 U.S.C. 112(a)¹ in the disclosure of the application, and (2) functional limitations (*i.e.*, claim limitations that define an element in terms of the function it performs without reciting the structure, materials, or acts that perform the function) are properly treated as means (or step) plus function limitations under 35 U.S.C. 112(f), and are sufficiently definite under 35 U.S.C. 112(b), as appropriate. These requirements are particularly relevant to computer-implemented functional claims.

The U.S. Court of Appeals for the Federal Circuit (“Federal Circuit”) has recognized a problem with broad functional claiming without adequate structural support in the specification. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (en banc) (overruling the Federal Circuit’s previous application of a “strong” presumption that claim limitations lacking the word “means” are not subject to § 112(f) to address the resulting “proliferation of functional claiming untethered to [§ 112(f)] and free of the strictures set forth in the statute”); *Function Media, LLC v. Google, Inc.*, 708 F.3d 1310, 1319 (Fed. Cir. 2013) (“Section [112(f)] is intended

⁴¹ Such justification may include, for example, an explanation of why the element contains subject matter that, *per se*, invokes eligibility concerns similar to those expressed by the Supreme Court with regard to the judicial exceptions. *See supra* note 5.

⁴² Similarly, in the rare circumstance in which a panel of administrative patent judges (or panel majority) believes that a claim reciting a tentative abstract idea should be treated as reciting an abstract idea, the matter should be brought to the attention of the PTAB leadership by a written request for clearance.

⁴³ *See* MPEP 2103 *et seq.* and 2106(III).

¹ Section 4 of the Leahy-Smith America Invents Act (AIA) designated pre-AIA 35 U.S.C. 112, ¶ 1 through 6, as 35 U.S.C. 112(a) through (f), effective as to applications filed on or after September 16, 2012. *See* Public Law 112–29, 4(c), 125 Stat. 284, 296 (2011). AIA 35 U.S.C. 112(a) and pre-AIA 35 U.S.C. 112, ¶ 1 are collectively referred to in this notice as 35 U.S.C. 112(a); AIA 35 U.S.C. 112(b) and pre-AIA 35 U.S.C. 112, ¶ 2 are collectively referred to in this notice as 35 U.S.C. 112(b); and AIA 35 U.S.C. 112(f) and pre-AIA 35 U.S.C. 112, ¶ 6 are collectively referred to in this notice as 35 U.S.C. 112(f).

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The *2019 Revised Patent Subject Matter Eligibility Guidance* (2019 PEG) published on January 7, 2019 (84 Fed. Reg. 50), and comments were solicited from the public.¹ Numerous comments were received, and have been reviewed. Using further explanation and examples, this update responds to the five major themes from the comments.² Note, the feedback received was primarily directed to examination procedures and, accordingly, this update focuses on clarifying practice for patent examiners. However, all USPTO personnel are expected to follow the guidance.³

In the discussion below, the response to each theme is addressed in a separate section as follows, including further explanation on:

- (I) evaluating whether a claim recites a judicial exception;
- (II) the groupings of abstract ideas enumerated in the 2019 PEG;
- (III) evaluating whether a judicial exception is integrated into a practical application;
- (IV) the *prima facie* case and the role of evidence with respect to eligibility rejections; and
- (V) the application of the 2019 PEG in the patent examining corps.

Three appendices are also attached. The first appendix (Appendix 1) provides new examples that are illustrative of major themes from the comments. The second appendix (Appendix 2) is a comprehensive index of examples for use with the 2019 PEG, including examples issued prior to the publication of the 2019 PEG. The third appendix (Appendix 3) lists and discusses selected eligibility cases from the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit.

I. Evaluating Whether A Claim Recites A Judicial Exception At Step 2A Prong One

The following discussion provides more information about how to determine whether a claim recites a judicial exception.

A. Meaning Of “Recites”

In Step 2A Prong One, the 2019 PEG instructs examiners to evaluate whether a claim recites a judicial exception, i.e., an abstract idea enumerated in Section I of the 2019 PEG, a law of nature, or a natural phenomenon. The 2019 PEG did not change the meaning of “recites” from how this term is used in the Manual of Patent Examining Procedure (MPEP).⁴ That is, a claim recites a judicial exception when the judicial exception is “set forth” or “described” in the claim. While the terms “set forth” and “describe” are thus both equated with “recite,” their different language is intended to indicate that there are two ways in which an exception can be recited in a claim. For instance, the claims in *Diamond v. Diehr* clearly stated a mathematical equation in the repetitively calculating step, such that the claims “set forth” an identifiable judicial exception, but the claims in *Alice Corp. v. CLS Bank*, “described” the concept of intermediated settlement without ever explicitly using the words “intermediated” or “settlement.”

Thus, when determining whether a claim “recites” a judicial exception, examiners should:

- evaluate the claim to determine whether it sets forth or describes an **abstract idea** in accordance with the examination instructions in the 2019 PEG and the groupings of abstract ideas that are further clarified in Section II of this update;
- evaluate the claim to determine whether it sets forth or describes a **product of nature** in accordance with the guidance in MPEP 2106.04(b) and (c), including the markedly different characteristics analysis; and

- evaluate the claim to determine whether it sets forth or describes a ***law of nature or a natural phenomenon other than a product of nature*** in accordance with the guidance in MPEP 2106.04(b).

Specific examples of how to perform these evaluations of whether a claim sets forth or describes an exception under the 2019 PEG are found in Examples 37-43 and 45-46 (abstract ideas), Examples 43 and 45 (laws of nature), and Examples 43-44 (products of nature). Additional examples of how to identify whether a claim recites a law of nature or natural phenomenon are found in the pre-PEG examples 9-18 and 28-31.

B. Multiple Judicial Exceptions Recited In A Claim

Clarification was requested on how claims reciting multiple judicial exceptions are treated. A claim can recite more than one judicial exception (i.e., abstract idea, law of nature, or natural phenomenon).⁵ In some claims, the multiple exceptions are distinct from each other, e.g., a first limitation describes a law of nature, and a second limitation elsewhere in the claim recites an abstract idea. In these cases, examiners should continue to follow existing guidance in MPEP 2106.05(II) when analyzing the claims for eligibility.⁶

Other claims may recite multiple abstract ideas, which may fall in the same or different groupings, or multiple laws of nature. In these cases, examiners should not parse the claim. For example, in a claim that includes a series of steps that recite mental steps as well as a mathematical calculation, an examiner should identify the claim as reciting both a mental process and a mathematical concept for Step 2A Prong One to make the analysis clear on the record. However, if possible, the examiner should consider the limitations together to be an abstract idea for Step 2A Prong Two and Step 2B (if necessary) rather than a plurality of separate abstract ideas to be analyzed individually.⁷ This is illustrated in, e.g., Example 45 (Controller for Injection Mold), and Example 46 (Livestock Management).

II. The Groupings Of Abstract Ideas Enumerated In The 2019 PEG

The 2019 PEG sets forth a test that distills the relevant case law to aid in examination, and does not attempt to articulate each and every decision. As further explained in the 2019 PEG, the Office has shifted its approach from the case-comparison approach in determining whether a claim recites an abstract idea and instead uses enumerated groupings of abstract ideas.⁸ The enumerated groupings are firmly rooted in Supreme Court precedent as well as Federal Circuit decisions interpreting that precedent. By grouping the abstract ideas, the 2019 PEG shifts examiners' focus from relying on individual cases to generally applying the wide body of case law spanning all technologies and claim types. In sum, the 2019 PEG synthesizes the holdings of various court decisions to facilitate examination.

Additional guidance on identifying abstract ideas enumerated in the 2019 PEG and their relationship to judicial decisions was requested. The 2019 PEG instructs examiners to refer to the groupings of abstract ideas enumerated in Section I of the 2019 PEG (i.e., mathematical concepts, certain methods of organizing human activities, and mental processes) in order to identify abstract ideas.⁹ These groupings are not mutually exclusive, i.e., some claims may recite limitations that fall within more than one abstract idea grouping or sub-grouping enumerated in the 2019 PEG. For example, a claim reciting performing mathematical calculations using a formula that could be practically performed in the human mind may be considered to fall within the mathematical concepts grouping and the mental process grouping. Examiners should identify at least one abstract

idea grouping, but preferably identify all groupings to the extent possible, if a claim limitation(s) is determined to fall within multiple groupings, and proceed with the analysis in Step 2A Prong Two. This is illustrated in, e.g., Example 45 (Controller for Injection Mold). Under the 2019 PEG, if an examiner has an application with a claim limitation that does not fall clearly within the enumerated groupings of abstract ideas, but the examiner nonetheless determines, based on a Supreme Court or Federal Circuit decision, that the claim limitation should be treated as reciting an abstract idea, the examiner should bring the application to the attention of their Technology Center (TC) Director, as described below in Section I.D.¹⁰ The following discussion is meant to provide more information about the enumerated groupings of abstract ideas.

A. Mathematical Concepts

The 2019 PEG defines “mathematical concepts” as mathematical relationships, mathematical formulas or equations, and mathematical calculations. Clarification was requested about the scope of the “mathematical concepts” grouping, and in particular, examples of each type of mathematical concept were requested.

Suggestions were made that the Office should distinguish between the types of math recited in claims when making an eligibility determination. After consideration, the current “mathematical concepts” grouping will be retained because it is consistent with the case law. The courts have declined to distinguish between the types of math recited in a claim when evaluating claims for eligibility. For example, in *Parker v. Flook*, the Court found that the claim recited a mathematical formula.¹¹ This determination was not altered by the fact that the math was being used to solve an engineering problem (i.e., updating an alarm limit during catalytic conversion processes).

When determining whether a claim recites a mathematical concept (i.e., mathematical relationships, mathematical formulas or equations, and mathematical calculations), examiners should consider whether the claim recites a mathematical concept or merely includes limitations that are based on or involve a mathematical concept. A claim does not recite a mathematical concept (i.e., the claim limitations do not fall within the mathematical concept grouping), if it is only based on or involves a mathematical concept.¹² For example, a limitation that is merely based on or involves a mathematical concept described in the specification may not be sufficient to fall into this grouping, provided the mathematical concept itself is not recited in the claim.¹³

Specific examples of claims reciting mathematical concepts issued with or after the 2019 PEG are found in Example 41 (Cryptographic Communications), Example 43 (Treating Kidney Disease), and Example 45 (Controller for Injection Molding).

i. “Mathematical Relationships”

A mathematical relationship is a relationship between variables or numbers. A mathematical relationship may be expressed in words or using mathematical symbols. For example, pressure (p) can be described as the ratio between the magnitude of the normal force (F) and area of the surface on contact (A), or it can be set forth in the form of an equation such as $p = F/A$.

Examples of mathematical relationships recited in a claim include:

- a relationship between reaction rate and temperature, which relationship can be expressed in the form of a formula called the Arrhenius equation, *Diamond v. Diehr*;¹⁴
- a conversion between binary-coded decimal and pure binary numerals, *Gottschalk v. Benson*;¹⁵ and

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- a mathematical relationship between enhanced directional radio activity and antenna conductor arrangement (i.e., the length of the conductors with respect to the operating wave length and the angle between the conductors), *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*¹⁶

ii. “Mathematical Formulas or Equations”

A claim that recites a numerical formula or equation will be considered as falling within the “mathematical concepts” grouping. In addition, there are instances where a formula or equation is written in text format that should also be considered as falling within this grouping. For example, the phrase “determining a ratio of A to B” is merely a textual replacement for the particular equation (ratio = A/B). Additionally, the phrase “calculating the force of the object by multiplying its mass by its acceleration” is a textual replacement for the particular equation ($F = ma$).

Examples of mathematical equations or formulas recited in a claim include:

- a Arrhenius equation, *Diamond v. Diehr*;¹⁷
- a formula for computing an alarm limit, *Parker v. Flook*;¹⁸ and
- a mathematical formula for hedging (claim 4), *Bilski v. Kappos*.¹⁹

iii. “Mathematical Calculations”

A claim that recites a mathematical calculation will be considered as falling within the “mathematical concepts” grouping. A mathematical calculation is a mathematical operation (such as multiplication) or an act of calculating using mathematical methods to determine a variable or number, e.g., performing an arithmetic operation such as exponentiation. There is no particular word or set of words that indicates a claim recites a mathematical calculation. That is, a claim does not have to recite the word “calculating” in order to be considered a mathematical calculation. For example, a step of “determining” a variable or number using mathematical methods or “performing” a mathematical operation may also be considered mathematical calculations when the broadest reasonable interpretation of the claim in light of the specification encompasses a mathematical calculation.

Examples of mathematical calculations recited in a claim include:

- performing a resampled statistical analysis to generate a resampled distribution, *SAP Am., Inc. v. InvestPic, LLC*;²⁰
- calculating a number representing an alarm limit value using the mathematical formula “ $B_1 = B_0 (1.0 - F) + PVL(F)$,” *Parker v. Flook*;²¹ and
- using a formula to convert geospatial coordinates into natural numbers, *Burnett v. Panasonic Corp.*²²

B. Certain Methods of Organizing Human Activity

Clarification was requested about the scope of the “certain methods of organizing human activity” grouping. In particular, examples of fundamental economic principles or practices, commercial or legal interactions, and managing personal behavior, relationships or interactions between people were requested.

The term “certain” qualifies the “certain methods of organizing human activity” grouping as a reminder of several important points. First, not all methods of organizing human activity are

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abstract ideas (e.g., “a defined set of steps for combining particular ingredients to create a drug formulation” is not a “certain method of organizing human activity”).²³ Second, this grouping is limited to activity that falls within the enumerated sub-groupings of fundamental economic principles or practices, commercial or legal interactions, managing personal behavior, and relationships or interactions between people, and is not to be expanded beyond these enumerated sub-groupings except in rare circumstances as explained in Section III(C) of the 2019 PEG. Finally, the sub-groupings encompass both activity of a single person (for example, a person following a set of instructions or a person signing a contract online) and activity that involves multiple people (such as a commercial interaction), and thus, certain activity between a person and a computer (for example a method of anonymous loan shopping that a person conducts using a mobile phone) may fall within the “certain methods of organizing human activity” grouping. The number of people involved in the activity is not dispositive as to whether a claim limitation falls within this grouping. Instead, the determination should be based on whether the activity itself falls within one of the sub-groupings.

i. “Fundamental Economic Practices or Principles”

Under the 2019 PEG, “fundamental economic principles or practices,” which describe subject matter relating to the economy and commerce, are considered to be a “certain method of organizing human activity.” According to the 2019 PEG, “fundamental economic principles or practices” include hedging, insurance, and mitigating risk. The term “fundamental” is not used in the sense of necessarily being “old” or “well-known,”²⁴ although being old or well-known may indicate that the practice is “fundamental.”²⁵

MPEP 2106.04(a)(2)(I) provides examples of “fundamental economic principles or practices.” Additional examples of “fundamental economic practices or principles” not discussed in this MPEP section include:

- local processing of payments for remotely purchased goods, *Inventor Holdings, LLC v. Bed Bath & Beyond, Inc.*;²⁶
- using a marking affixed to the outside of a mail object to communicate information about the mail object, i.e., the sender, recipient, and contents of the mail object, *Secured Mail Solutions LLC v. Universal Wilde, Inc.*;²⁷ and
- placing an order based on displayed market information, *Trading Technologies Int’l, Inc. v. IBG LLC*.²⁸

ii. “Commercial or Legal Interactions”

According to the 2019 PEG, “commercial interactions” or “legal interactions” include subject matter relating to agreements in the form of contracts, legal obligations, advertising, marketing or sales activities or behaviors, and business relations.

Examples of subject matter where the commercial or legal interaction is an agreement in the form of contracts include:

- a transaction performance guaranty, which is a contractual relationship, *buySAFE, Inc. v. Google, Inc.*;²⁹ and

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- processing insurance claims for a covered loss or policy event under an insurance policy (i.e., an agreement in the form of a contract), *Accenture Global Services GmbH v. Guidewire Software, Inc.*³⁰

Examples of subject matter where the commercial or legal interaction is a legal obligation include:

- tax-free exchanges of real estate, where the exchange is a legal obligation, *Fort Properties, Inc. v. American Master Lease LLC*;³¹ and
- arbitration (i.e., resolving a legal dispute between two parties using an arbitrator), *In re Comiskey*.³²

Examples of subject matter where the commercial or legal interaction is advertising, marketing or sales activities or behaviors include:

- using advertising as an exchange or currency, *Ultramercial, Inc. v. Hulu, LLC*;³³
- offer-based price optimization, which pertains to marketing, *OIP Techs., Inc. v. Amazon.com, Inc.*;³⁴ and
- structuring of a sales force or marketing company, which pertains to marketing or sales activities or behaviors, *In re Ferguson*.³⁵

Examples of subject matter where the commercial or legal interaction is business relations include:

- processing a credit application between a customer and dealer, where the business relation is the relationship between the customer and the dealer during the vehicle purchase, *Credit Acceptance Corp. v. Westlake Services*;³⁶ and
- processing information through a clearinghouse, where the business relation is the relationship between a party that submitted a credit application (e.g., a car dealer) and funding sources (e.g., banks) when processing credit applications, *Dealertrack v. Huber*.³⁷

For additional discussion and examples of commercial or legal interactions, see MPEP 2106.04(a)(2)(II)(A)-(B).

iii. “Managing Personal Behavior or Relationships or Interactions Between People”

According to the 2019 PEG, “managing personal behavior or relationships or interactions between people” includes social activities, teaching, and following rules or instructions. Examples of these sub-groups include subject matter such as:

- a set of rules for playing a dice game, *In re Marco Guldenaar Holding B.V.*;³⁸
- voting, verifying the vote, and submitting the vote for tabulation, *Voter Verified, Inc. v. Election Systems & Software LLC*;³⁹
- assigning hair designs to balance head shape, *In re Brown*;⁴⁰ and
- a series of instructions of how to hedge risk, *Bilski v. Kappos*.⁴¹

For additional examples relating to managing human behavior, see MPEP 2106.04(a)(2)(II)(C).

C. Mental Processes

Under the 2019 PEG, the “mental processes” grouping is defined as concepts performed in the human mind, and examples of mental processes include observations, evaluations, judgments, and opinions. Because both product and process claims may recite a “mental process,” the phrase “mental processes” should be understood as referring to the type of abstract idea, and not to the statutory category of the claim.⁴² Additional information was requested about how an examiner evaluates whether a claim recites a mental process. Accordingly, the following discussion is meant to guide examiners and provide more information on how to determine whether a claim recites a mental process. Examiners should keep in mind the following points when performing this evaluation.

i. *A Claim With Limitation(s) That Cannot Practically Be Performed In The Human Mind Does Not Recite A Mental Process*

Claims do not recite a mental process when they do not contain limitations that can practically be performed in the human mind, for instance when the human mind is not equipped to perform the claim limitations.⁴³ Examples of claims that do not recite mental processes because they cannot be practically performed in the human mind include:

- a claim to a method for calculating an absolute position of a GPS receiver and an absolute time of reception of satellite signals, where the claimed GPS receiver calculated pseudoranges that estimated the distance from the GPS receiver to a plurality of satellites, *SiRF Technology, Inc. v. International Trade Commission*;⁴⁴
- a claim to detecting suspicious activity by using network monitors and analyzing network packets, *SRI Int'l, Inc. v. Cisco Systems, Inc.*;⁴⁵
- a claim to a specific data encryption method for computer communication involving a several-step manipulation of data, *Synopsys, Inc. v. Mentor Graphics Corp.* (distinguishing the claims in *TQP Development, LLC v. Intuit Inc.*);⁴⁶ and
- a claim to a method for rendering a halftone image of a digital image by comparing, pixel by pixel, the digital image against a blue noise mask, where the method required the manipulation of computer data structures (e.g., the pixels of a digital image and a two-dimensional array known as a mask) and the output of a modified computer data structure (a halftoned digital image), *Research Corp. Techs. v. Microsoft Corp.*⁴⁷

Specific examples of claims that do not recite a mental process issued with or after the 2019 PEG are found in Example 37 (Relocation of Icons on a Graphical User Interface – claim 2), Example 38 (Simulating an Analog Audio Mixer), and Example 39 (Method for Training a Neural Network for Facial Detection).

In contrast, claims do recite a mental process when they contain limitations that can practically be performed in the human mind, including for example, observations, evaluations, judgments, and opinions. Examples of claims that recite mental processes include:

- a claim to “collecting information, analyzing it, and displaying certain results of the collection and analysis,” where the data analysis steps are recited at a high level of generality such that they could practically be performed in the human mind, *Electric Power Group, LLC v. Alstom, S.A.*;⁴⁸

- claims to “comparing BRCA sequences and determining the existence of alterations,” where the claims cover any way of comparing BRCA sequences such that the comparison steps can practically be performed in the human mind, *University of Utah Research Foundation v. Ambry Genetics Corp.*,⁴⁹
- a claim to collecting and comparing known information (claim 1), which are steps that can be practically performed in the human mind, *Classen Immunotherapies, Inc. v. Biogen IDEC*,⁵⁰ and
- a claim to identifying head shape and applying hair designs, which is a process that can be practically performed in the human mind, *In re Brown*.⁵¹

Specific examples of claims that do recite a mental process issued with or after the 2019 PEG are found in Example 37 (Relocation of Icons on a Graphical User Interface – claims 1 and 3), Example 40 (Adaptive Monitoring of Network Traffic Data), Example 43 (Treating Kidney Disease), Example 45 (Controller for Injection Molding), and Example 46 (Livestock Management).

ii. *A Claim That Requires A Computer May Still Recite A Mental Process*

Claims can recite a mental process even if they are claimed as being performed on a computer.⁵² Suggestions were made that an examiner should determine that a claim, when given its broadest reasonable interpretation, recites a mental process only when the claim is performed *entirely* in the human mind. After consideration, this suggestion will not be adopted, and the current “mental processes” grouping in the 2019 PEG will be retained, since it is consistent with current case law. The courts have found claims requiring a generic computer or nominally reciting a generic computer may still recite a mental process even though the claim limitations are not performed entirely in the human mind.⁵³

In evaluating whether a claim that requires a generic computer recites a mental process, examiners should carefully consider the broadest reasonable interpretation of the claim in light of the specification. By way of example, examiners may review the specification to determine if the underlying claimed invention is described as a concept that is performed in the human mind and applicant is merely claiming that concept performed 1) on a generic computer, 2) in a computer environment or 3) is merely using a computer as a tool to perform the concept. In these situations, the claim is considered to recite a mental process. For instance, in *Voter Verified, Inc. v. Election Systems & Software LLC*, the Federal Circuit relied upon the specification in explaining that the claimed steps of voting, verifying the vote, and submitting the vote for tabulation are human cognitive actions that humans have performed for hundreds of years despite the fact that the steps in the claim were performed on a computer.⁵⁴

Furthermore, examiners should keep in mind that both product claims (e.g., computer system, computer-readable medium, etc.) and process claims may recite mental processes.⁵⁵ For example, in *Mortgage Grader, Inc. v. First Choice Loan Servs., Inc.*, the patentee claimed a computer-implemented system and a method for enabling borrowers to anonymously shop for loan packages offered by a plurality of lenders, comprising a database that stores loan package data from the lenders, and a computer system providing an interface and a grading module. The Federal Circuit held that the computer-implemented system and method for “anonymous loan shopping” was an abstract idea because it could be “performed by humans without a computer.”⁵⁶

October 2019 Update: Subject Matter Eligibility*iii. A Claim That Encompasses A Human Performing The Step(s) Mentally With The Aid Of A Pen And Paper Recites A Mental Process*

If a claim recites a limitation that can practically be performed in the human mind, the limitation falls within the mental processes grouping, and the claim recites an abstract idea.⁵⁷ The use of a physical aid (i.e., the pen and paper) to help perform a mental step (e.g., a mathematical calculation) does not negate the mental nature of this limitation.⁵⁸ For instance, Example 45 (Controller for Injection Molding) illustrates how a claim that encompasses a human performing a step mentally with a physical aid recites a mental process. *CyberSource Corp. v. Retail Decisions, Inc.* provides another example. In that case, the court determined that the claimed step of “constructing a map of credit card numbers” was a limitation that was able to be performed “by writing down a list of credit card transactions made from a particular IP address.” In making this determination, the court looked to the specification, which disclosed that the claimed map was nothing more than a listing of several (e.g., four) credit card transactions. The court determined that this step was able to be performed mentally with a pen and paper, and therefore, qualifies as a mental process.⁵⁹ While a claim limitation to a process that “can be performed in the human mind, or by a human using a pen and paper” qualifies as a mental process, a claim limitation that “could not, as a practical matter, be performed entirely in a human’s mind” (even if aided with pen and paper) would not qualify as a mental process.⁶⁰

D. Tentative Abstract Idea Procedure

The 2019 PEG sets forth a procedure for handling tentative abstract ideas. Clarification was requested about this procedure (e.g., whether the Office will notify the public if the procedure is used, whether an interview with a TC director will be granted, etc.), and suggestions were made for modifications to this procedure. The following discussion provides additional clarification regarding this procedure.

The TC Director will give approval for any subject matter eligibility rejection of a claim including a tentative abstract idea using the procedure in the 2019 PEG. The ensuing Office action will identify that the claim(s) are directed to a previously non-enumerated abstract idea via form paragraph 7.05.017 and include the TC Director’s signature. Before signature, the TC Director will inform Patents Management that this procedure has been used. Once such an Office action issues, the public will be notified, for example, on USPTO.GOV/PatentEligibility.

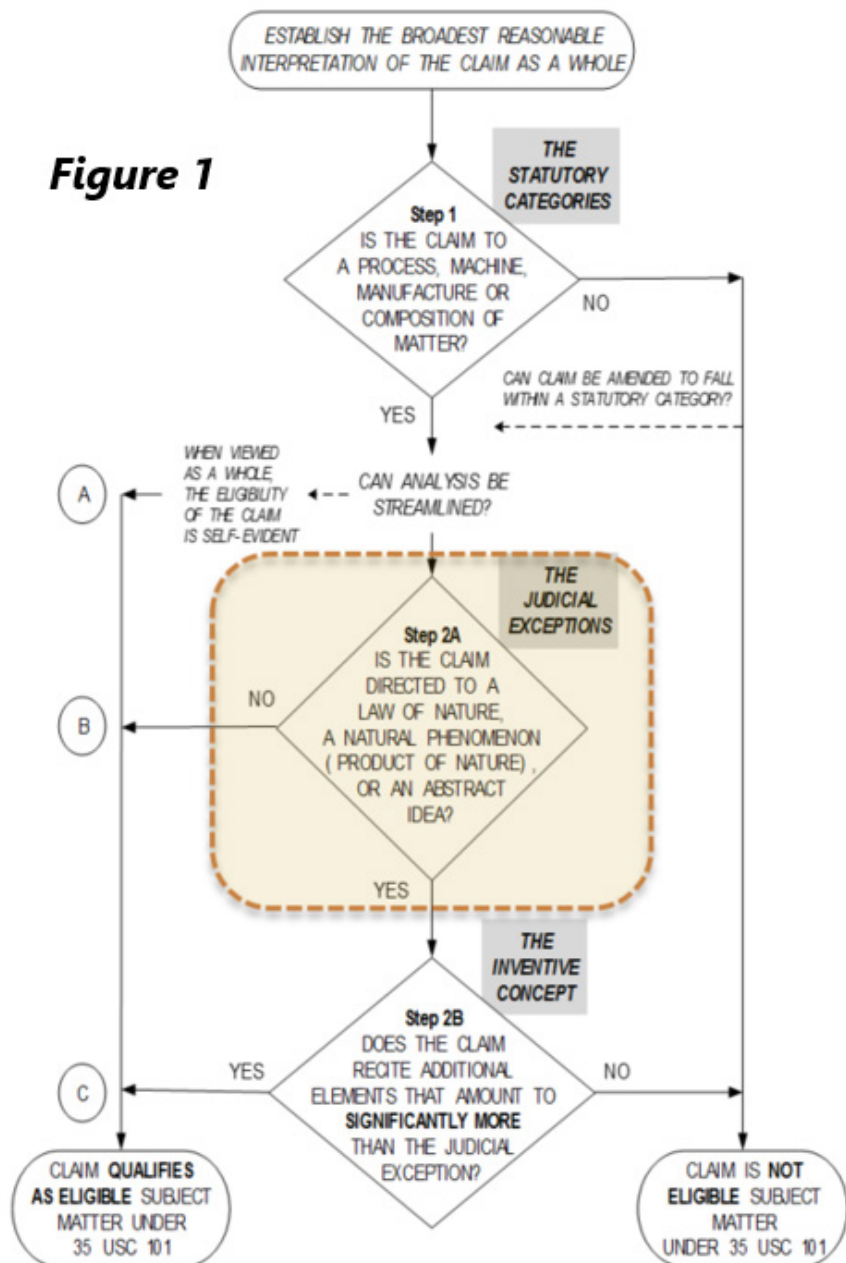
In response to a rejection based on failure to claim patent-eligible subject matter, an interview with the examiner may be conducted, which may help advance prosecution and identify patent eligible subject matter.⁶¹ For applications in which an abstract idea has been identified using the tentative abstract idea procedure, an interview with the TC Director that provided approval is not necessary because the examiner retains the authority to withdraw or maintain rejection upon consideration of applicant’s reply. The examiner is not required to obtain TC Director approval to withdraw or maintain such a § 101 subject matter eligibility rejection.

III. Evaluating Whether A Judicial Exception Is Integrated Into A Practical Application At Step 2A Prong Two

A. Integration into a Practical Application

According to the 2019 PEG, the question of whether a claim is “directed to” a judicial exception in Step 2A is now evaluated using a two-prong inquiry. Prong One, which is discussed in Section I of this Update, asks if the claim “recites” an abstract idea, law of nature, or natural phenomenon. Under that prong, the mere inclusion of a judicial exception such as a mathematical formula (which is one of the mathematical concepts identified as an abstract idea in Section I of the PEG) in a claim means that the claim “recites” a judicial exception. However, mere recitation of a judicial exception does not mean that the claim is “directed to” that judicial exception under Step 2A Prong Two. Instead, under Prong Two, a claim that recites a judicial exception is not directed to that judicial exception, if the claim as a whole “integrates the recited judicial exception into a practical application of that exception.”⁶² Prong Two thus distinguishes claims that are “directed to” the recited judicial exception from claims that are not “directed to” the recited judicial exception.

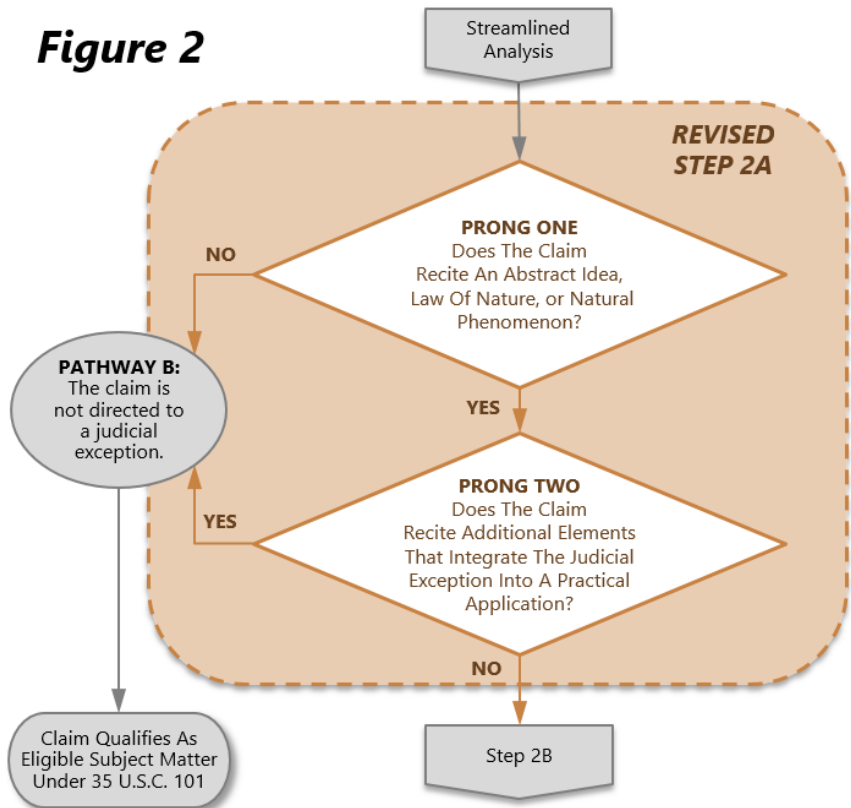
Because the 2019 PEG did not change the overall subject matter eligibility analysis, no changes have been made to the existing eligibility flowchart in MPEP 2106(III), which is reproduced in Figure 1 (at right).



Instead, a new mini-flowchart was created to depict the two-prong analysis that is now performed in order to answer the Step 2A inquiry. This mini-flowchart, which was used in USPTO training on the 2019 PEG, is also reproduced in Figure 2 (at right). These figures demonstrate how the revised Step 2A analysis created by the 2019 PEG fits into the overall eligibility analysis set forth in the MPEP. As shown in Figure 2 and described in the 2019 PEG at Section III, a claim reciting a judicial exception is now eligible at revised Step 2A unless that exception is not integrated into a practical application of the exception.⁶³

As explained in the 2019 PEG, the evaluation of Prong Two requires the use of the considerations (e.g. improving technology, effecting a particular treatment or prophylaxis, implementing with a particular machine, etc.) identified by the Supreme Court and the Federal Circuit, to ensure that the claim as a whole “integrates [the] judicial exception into a practical application [that] will apply, rely on, or use the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception.”⁶⁴ These considerations are set forth in the 2019 PEG, MPEP 2106.05(a) through (c), and MPEP 2106.05(e) through (h). Note, a specific way of achieving a result is not a stand-alone consideration in Step 2A Prong Two. However, the specificity of the claim limitations is relevant to the evaluation of several considerations including the use of a particular machine, particular transformation and whether the limitations are mere instructions to apply an exception.⁶⁵ If the claim integrates the judicial exception into a practical application based upon evaluation of these considerations, the additional limitations impose a meaningful limit on the judicial exception, and the claim is eligible at Step 2A.

For example, if the additional limitations reflect an improvement in the functioning of a computer, or an improvement to another technology or technical field, the claim integrates the judicial exception into a practical application and thus imposes a meaningful limit on the judicial exception. No further analysis is required. The claim is eligible at Step 2A. For instance, in *SRI International, Inc. v. Cisco Systems, Inc.*, the court concluded the claim recited using a plurality of network monitors to analyze specific network traffic data and integrate generated reports from the monitors to identify hackers and intruders on the network constituted an improvement in computer network technology.⁶⁶ Since the claim improves technology, the claim imposes meaningful limits on any recited judicial exception, and the claim would be eligible under the 2019 PEG at least at Step 2A Prong Two. Conversely, not all claims that recite computer components, for example, integrate a judicial exception into a practical application based upon evaluation of the considerations. In *Alice*



Corp. Pty. Ltd. v. CLS Bank Int'l, the Supreme Court determined that the claim limitations “data processing system,” “communications controller,” and “data storage unit” were generic computer components that amounted to mere instructions to implement the abstract idea on a computer.⁶⁷ Such limitations would not be sufficient to demonstrate integration of a judicial exception into a practical application, and accordingly the analysis of the claims must proceed to Step 2B.

As also explained in the 2019 PEG, the Prong Two analysis considers the claim as a whole. That is, the limitations containing the judicial exception as well as the additional elements in the claim besides the judicial exception need to be evaluated together to determine whether the claim integrates the judicial exception into a practical application. The additional limitations should not be evaluated in a vacuum, completely separate from the recited judicial exception. Instead, the analysis should take into consideration all the claim limitations and how those limitations interact and impact each other when evaluating whether the exception is integrated into a practical application. For example in *Bascom Global Internet Servs., Inc. v. AT&T Mobility LLC*, the court determined the claim recited the abstract idea of “filtering.”⁶⁸ However, it concluded the claimed invention improved technology because the filtering tool was installed at a specific location, remote from the end-users, with customizable filtering features specific to each end user which provided both the benefits of a filter at a local computer and on an ISP server.⁶⁹ In determining whether the claimed invention improves technology, the court considered the filtering limitations in combination with the remaining limitations.

B. An Improvement in the Functioning of a Computer or an Improvement to Other Technology or Technical Field

An important consideration to evaluate when determining whether the claim as a whole integrates a judicial exception into a practical application is whether the claimed invention improves the functioning of a computer or other technology. The courts have not provided an explicit test for this consideration. However, MPEP 2106.04(a) and 2106.05(a) provide a detailed explanation of how to perform this analysis. In short, first the specification should be evaluated to determine if the disclosure provides sufficient details such that one of ordinary skill in the art would recognize the claimed invention as providing an improvement. The specification need not explicitly set forth the improvement, but it must describe the invention such that the improvement would be apparent to one of ordinary skill in the art. Conversely, if the specification explicitly sets forth an improvement but in a conclusory manner (i.e., a bare assertion of an improvement without the detail necessary to be apparent to a person of ordinary skill in the art), the examiner should not determine the claim improves technology. Second, if the specification sets forth an improvement in technology, the claim must be evaluated to ensure that the claim itself reflects the disclosed improvement. That is, the claim includes the components or steps of the invention that provide the improvement described in the specification. The claim itself does not need to explicitly recite the improvement described in the specification (e.g., “thereby increasing the bandwidth of the channel”).

The improvement analysis under the 2019 PEG differs in some respects from prior guidance. Under prior guidance, at both Steps 2A and 2B, the improvements analysis considered whether the claimed invention improves upon conventional technology.⁷⁰ Under the 2019 PEG, in contrast, the “improvements” analysis in Step 2A determines whether the claim pertains to an improvement to the functioning of a computer or to another technology without reference to what is well-understood, routine, conventional activity. That is, the claimed invention may integrate the judicial exception into a practical application by demonstrating that it improves the relevant existing

technology although it may not be an improvement over well-understood, routine, conventional activity.

Consideration of improvements is relevant to the integration analysis regardless of the technology of the claimed invention. That is, the consideration applies equally whether it is a computer-implemented invention, an invention in the life sciences, or any other technology. See, e.g., *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, in which the court noted that a claimed process for preserving hepatocytes could be eligible as an improvement to technology because the claim achieved a new and improved way for preserving hepatocyte cells for later use, even though the claim is based on the discovery of something natural.⁷¹ Notably, the court did not distinguish between the types of technology when determining that the invention improved technology. However, it is important to keep in mind that an improvement in the judicial exception itself (e.g., a recited fundamental economic concept) is not an improvement in technology. For example, in *Trading Technologies Int'l v. IBG LLC*, the court determined that the claim simply provided a trader with more information to facilitate market trades, which improved the business process of market trading but did not improve computers or technology.⁷² Note, there is no requirement for the judicial exception to provide the improvement. The improvement can be provided by one or more additional elements (as in *Diehr*), or by the additional element(s) in combination with the recited judicial exception (as in *Finjan*).⁷³ Thus, it is important for examiners to analyze the claim as a whole when determining whether the claim provides an improvement to the functioning of computers or an improvement to other technology or technical field.

During examination, the examiner should analyze the “improvements” consideration by evaluating the specification and the claims to ensure that a technical explanation of the asserted improvement is present in the specification, and that the claim reflects the asserted improvement. Generally, examiners are not expected to make a qualitative judgment on the merits of the asserted improvement. If the examiner concludes the disclosed invention does not improve technology, the burden shifts to applicant to provide persuasive arguments supported by any necessary evidence to demonstrate that one of ordinary skill in the art would understand that the disclosed invention improves technology. Any such evidence submitted under 37 C.F.R. § 1.132 must establish what the specification would convey to one of ordinary skill in the art and cannot be used to supplement the specification.⁷⁴ For example, in response to a rejection under 35 U.S.C. § 101, an applicant could submit a declaration under § 1.132 providing testimony on how one of ordinary skill in the art would interpret the disclosed invention as improving technology and the underlying factual basis for that conclusion.

C. Applying or Using a Judicial Exception to Effect a Particular Treatment or Prophylaxis for a Disease or Medical Condition

The 2019 PEG includes a “treatment/prophylaxis” consideration, under which a claim can integrate a judicial exception into a practical application by applying or using the judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition. This consideration originated as part of the “Other Meaningful Limitations” consideration discussed in MPEP 2106.05(e), and was also based on the USPTO’s June 2018 *Vanda* Memorandum which stated that method of treatment claims that practically apply natural relationships are eligible at Step 2A.⁷⁵ This consideration encompasses the integration of any type of judicial exception into a practical application, including abstract ideas such as the mental comparison of immunization-related information in *Classen Immunotherapies, Inc. v. Biogen IDEC*, which was practically applied by actually immunizing mammals in accordance with a particular immunization schedule.⁷⁶ This

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consideration encompasses both treatment and prophylaxis limitations, including, *e.g.*, acupuncture, administration of medication, dialysis, organ transplants, phototherapy, physiotherapy, radiation therapy, surgery, and the like.

When determining whether a claim applies or uses a recited judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition, the following factors are relevant.

i. *The Particularity Or Generality Of The Treatment Or Prophylaxis*

The treatment or prophylaxis limitation must be “particular,” i.e., specifically identified so that it does not encompass all applications of the judicial exception(s). For example, consider a claim that recites mentally analyzing information to identify if a patient has a genotype associated with poor metabolism of beta blocker medications. This falls within the mental process grouping of abstract ideas enumerated in Section I of the 2019 PEG. The claim also recites “administering a lower than normal dosage of a beta blocker medication to a patient identified as having the poor metabolizer genotype.” This administration step is particular, and it integrates the mental analysis step into a practical application. Conversely, consider a claim that recites the same abstract idea and “administering a suitable medication to a patient.” This administration step is not particular, and is instead merely instructions to “apply” the exception in a generic way. Thus, the administration step does not integrate the mental analysis step into a practical application.

ii. *Whether The Limitation(s) Have More Than A Nominal Or Insignificant Relationship To The Exception(s)*

The treatment or prophylaxis limitation must have more than a nominal or insignificant relationship to the exception(s). For example, consider a claim that recites a natural correlation (law of nature) between blood glucose levels over 250 mg/dl and the risk of developing ketoacidosis (a life-threatening medical condition). The claim also recites “treating a patient having a blood glucose level over 250 mg/dl with insulin.” This administration step is particular and integrates the law of nature into a practical application. Alternatively, consider a claim that recites the same law of nature and also recites “treating a patient having a blood glucose level over 250 mg/dl with aspirin.” Aspirin is not known in the art as a treatment for ketoacidosis or diabetes, although some patients with diabetes may be on aspirin therapy for other medical reasons (*e.g.*, to control pain or inflammation, or to prevent blood clots). In the context of this claim and the recited correlation between high blood glucose levels and the risk of ketoacidosis, administration of aspirin has at best a nominal connection to the law of nature, because aspirin does not treat or prevent ketoacidosis. This step therefore does not apply or use the exception in any meaningful way. Thus, this step of administering aspirin does not integrate the law of nature into a practical application.

iii. *Whether The Limitation(s) Are Merely Extra-Solution Activity Or A Field Of Use*

The treatment or prophylaxis limitation must impose meaningful limits on the judicial exception, and cannot be extra-solution activity or a field-of-use. For example, consider a claim that recites (a) administering rabies and feline leukemia vaccines to a first group of domestic cats in accordance with different vaccination schedules, and (b) analyzing information about the vaccination schedules and whether the cats later developed chronic immune-mediated disorders to determine a lowest-risk vaccination schedule. Step (b) falls within the mental process grouping of abstract ideas enumerated in Section I of the 2019 PEG. While step (a) administers vaccines to the cats, this administration is performed in order to gather data for the mental analysis step, and is a necessary precursor for all uses of the recited exception. It is thus extra-solution activity, and does not

integrate the judicial exception into a practical application. Conversely, consider a claim reciting the same steps (a) and (b), but also recites step (c) “vaccinating a second group of domestic cats in accordance with the lowest-risk vaccination schedule.” Step (c) applies the exception, in that the information from the mental analysis in step (b) is used to alter the order and timing of the vaccinations so that the second group of cats have a lower risk of developing chronic immune-mediated disorders. Step (c) thus integrates the abstract idea into a practical application.

D. Other Considerations in Step 2A, Prong Two

As discussed *supra* in Section III(A), the 2019 PEG identifies several other considerations in Step 2A Prong Two in addition to those already discussed. Considerations that may indicate integration include implementing the judicial exception with a particular machine or manufacture, effecting a particular transformation or reduction of an article, and applying the judicial exception in some other meaningful way. Considerations that may not indicate integration include merely reciting the words “apply it” or an equivalent, adding extra-solution activity, and generally linking the use of the judicial exception to a particular technological environment. These considerations have not changed from the guidance provided prior to the 2019 PEG except the improvements analysis discussed above in Section III(B) and extra-solution activity discussed below. See MPEP 2106.05(b)-2106.05(h) for more information and examples for each of these considerations.

The “extra-solution activity” consideration listed above has been slightly modified. MPEP 2106.05(g) explains, in the context of Step 2B, that whether a limitation is well-known is a factor to consider when determining if a limitation is extra-solution activity. However, well-known, routine, conventional activity is not a consideration at Step 2A in the 2019 PEG. Therefore, whether a claim limitation is extra-solution activity will not be based upon whether the limitation is well-known. Instead well-understood, routine, conventional activity will only be considered if the analysis proceeds to Step 2B. For specific examples of extra-solution activity that are unconventional, see Example 45 (Controller for Injection Mold).

IV. Requirements Of A *Prima Facie* Case

Suggestions were made that the Office emphasize the examiner’s burden of establishing a *prima facie* case when making a subject matter eligibility rejection. Accordingly, the following discussion reiterates the requirements of a *prima facie* case.

The legal concept of *prima facie* case is a procedural tool of patent examination, which allocates the burdens going forward between the examiner and the applicant. MPEP § 2106.07 discusses the requirements of a *prima facie* case of ineligibility. In particular, the initial burden is on the examiner to explain why a claim or claims are ineligible for patenting clearly and specifically, so that the applicant has sufficient notice and is able to effectively respond.⁷⁷ Examiners should review the record as a whole and make subject matter eligibility decisions on a claim-by-claim basis in accordance with the broadest reasonable interpretation of the claims.⁷⁸ Once the examiner has satisfied the initial burden, the burden of coming forward with evidence or argument shifts to the applicant. When evaluating a response, examiners must carefully consider all of applicant’s arguments and evidence rebutting the subject matter eligibility rejection. If applicant has amended the claim, examiners should determine the amended claim’s broadest reasonable interpretation and again perform the subject matter eligibility analysis.

MPEP 2106.07(a) provides a discussion of how to formulate a subject matter eligibility rejection.⁷⁹ Whenever practicable, examiners should indicate how subject matter eligibility rejections might be

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overcome. In light of the 2019 PEG, a “Step 2B” rejection based on a failure to claim an invention that is directed to patent-eligible subject matter (i.e., the claim is directed to a judicial exception without providing an inventive concept/significantly more at Step 2B of the eligibility analysis) should explain the following:

- First, the rejection should identify the judicial exception (i.e., abstract idea enumerated in Section I of the 2019 PEG, laws of nature, or a natural phenomenon) by referring to *what is recited* (i.e., set forth or described) in the claim and *explaining why* it is considered to be an exception (Step 2A Prong One). There is no requirement for the examiner to provide further support, such as publications or an affidavit or declaration under 37 CFR 1.104(d)(2), for the conclusion that a claim recites a judicial exception.⁸⁰
 - For abstract ideas, the rejection should explain why a specific limitation(s) recited in the claim falls within one of the enumerated groupings of abstract ideas (i.e., mathematical concepts, mental processes, or certain methods of organizing human activity) or provide a justification for why a specific limitation(s) recited in the claim is being treated as an abstract idea if it does not fall within the enumerated groupings of abstract ideas in accordance with the “tentative abstract idea” procedure in the 2019 PEG.
 - For a law of nature or a natural phenomenon, there has been no change in the type of explanation that should be provided in a rejection (i.e., the rejection should identify the law of nature or natural phenomenon as it is recited (i.e., set forth or described) in the claim and explain using a reasoned rationale why it is considered to be a law of nature or natural phenomenon).⁸¹
- Second, the rejection should *identify* any additional elements recited in the claim beyond the judicial exception and *evaluate* the integration of the judicial exception into a practical application *by explaining* that 1) there are no additional elements in the claim; or 2) the claim as a whole, looking at the additional elements individually and in combination, does not integrate the judicial exception into a practical application using the considerations set forth in the 2019 PEG (Step 2A Prong Two).
- Finally, the examiner should *explain why* the additional elements, taken individually and in combination, do not result in the claim, as a whole, amounting to significantly more than the exception (Step 2B).⁸² For instance, when the examiner has concluded that certain claim elements recite well-understood, routine, conventional activity in the relevant field, the examiner must expressly support such a rejection in writing with one of the four options specified in Section III.A. of the *Berkheimer* Memorandum.⁸³

If applicant challenges the examiner's findings, but the examiner deems it appropriate to maintain the rejection, the examiner must provide a rebuttal in the next Office action. For more information on evaluating applicant's response, *see* MPEP 2106.07(b). Applicant may timely submit evidence traversing a subject matter eligibility rejection according to the procedures set forth in MPEP 716.01 and 37 CFR 1.132.

V. Application Of The 2019 PEG In The Patent Examining Corps

Various suggestions were made as to the need for further guidance and examples (particularly in the area of life sciences) and more examiner training. The USPTO has already taken steps to enhance examiners' understanding of the revised eligibility guidance, and will continue to work

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with examiners as part of its ongoing efforts to enhance patent quality. The following discussion describes efforts that have been made so far to provide examiners with appropriate guidance and training on the application of the 2019 PEG. The following discussion also addresses concerns raised regarding applicants' options in responding to a subject matter eligibility rejection under the 2019 PEG.

Guidance Materials. The USPTO's current eligibility guidance includes: the 2019 PEG; the *Berkheimer* Memorandum; *Memorandum - Recent Subject Matter Eligibility Decisions*; the *Finjan* Memorandum;⁸⁴ MPEP Sections §§ 2103-2106;⁸⁵ *Subject Matter Eligibility Examples: Abstract Ideas* (Examples 37-42, issued January 7, 2019); and the examples contained in Appendix 1 to this update.⁸⁶ The examples are intended to illustrate the proper application of the eligibility analysis to a variety of claims in multiple technologies, and to guide examiners in evaluating eligibility in a consistent manner across the corps. The recently issued examples (i.e., examples 37-46) illustrate how to apply the 2019 PEG to analyze various fact patterns. Examples issued prior to the 2019 PEG do not apply the Step 2A Prong Two analysis in the 2019 PEG, however the ultimate results of eligibility or ineligibility for each example may still be relied upon because they have not changed. To assist examiners in understanding the principles discussed in the 2019 PEG and illustrated in the examples, Appendix 2 hereto is a comprehensive index of the examples, which provides an overview of the relevance of Examples 1-46 under the 2019 PEG. In particular, the index provides consolidated information on each example including the type of judicial exception involved, which examples provide a practical application or significantly more analysis, and the considerations that are evaluated in each example. For instance, the index explains that Example 3 (Digital Image Processing) contains a claim reciting a mathematical relationship that is eligible under the "improvements to the functioning of a computer or other technology" consideration. While published Example 3 indicates that this claim is eligible at Step 2B, the index explains that under the 2019 PEG, the same "improvements" consideration makes the claim eligible at Step 2A Prong Two.

Training. The examining corps was trained on the 2019 PEG in January – February 2019. Training was conducted in a variety of modalities, including instructor-led training and computer-based training. The training materials including slides are posted on the Office website. The computer-based training was designed to provide an introduction and overview of the 2019 PEG for examiners that do not regularly encounter subject matter eligibility issues. Examiners that regularly examine applications with subject matter eligibility issues received an advanced module led by an instructor that provided an in-depth discussion of the 2019 PEG and a subset of examples 37-42. The USPTO has continued to engage examiners regarding implementation of the 2019 PEG through art unit level Quality Enhancement Meetings. Presently, the USPTO is in the process of ascertaining what further training is appropriate.

Applicant Response. Concern was expressed regarding the fact that failure by USPTO personnel to follow the 2019 PEG is not, in itself, a proper basis for an appeal or a petition.⁸⁷ While the 2019 PEG does not constitute substantive rulemaking and does not have the force and effect of law, the 2019 PEG does constitute Office guidance and, accordingly, USPTO personnel are expected to follow it. As with any rejection, every applicant whose claims have been twice rejected, may appeal from the decision of the examiner to the Patent Trial and Appeal Board, and an applicant may rely upon the 2019 PEG in support of his or her argument that a rejection under § 101 is in error. It is the rejection under § 101, and not any alleged failure to comply with the 2019 PEG, that is reviewed by the Patent Trial and Appeal Board. Applicants also are encouraged to employ other courses of action available

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for engaging an examiner to obtain prompt resolution of any outstanding subject matter eligibility rejection or issues of compliance with the 2019 PEG (e.g., request an interview, contact the Supervisory Patent Examiner (SPE), pre-appeal brief review request).

¹ The current guidance documents on subject matter eligibility, including the 2019 PEG and the examples, all examiner training materials to date, and the public comments, are *available at* <https://www.uspto.gov/PatentEligibility>.

² Many responses appeared to be form letters from individuals that followed one of several formats.

³ 84 Fed. Reg. at 51.

⁴ The 2019 PEG supersedes MPEP 2106.04(II) (Eligibility Step 2A: Whether a Claim Is Directed to a Judicial Exception) to the extent it equates claims “reciting” a judicial exception with claims “directed to” a judicial exception. 84 Fed. Reg. at 51. However, the meaning of “recites”, which is “set forth or “describes” as explained in MPEP 2106.04(II), was not superseded by the 2019 PEG.

⁵ See *Genetic Techs. Ltd. v. Merial LLC*, 818 F.3d 1369, 1374-75, 1379 (Fed. Cir. 2016) (Claim to a method for analyzing DNA recited both the law of nature of linkage disequilibrium and the mental process of examining a non-coding region to detect an allele in the coding region).

⁶ If a claim recites a limitation(s) that falls under several exceptions (e.g., a law of nature or an abstract idea), it is sufficient for the examiner to identify that the claimed concept (the specific claim limitation(s) that the examiner believes may recite an exception) aligns with at least one judicial exception. See MPEP 2106.04.

⁷ See MPEP 2106.04(II).

⁸ 84 Fed. Reg. at 51-52.

⁹ 84 Fed. Reg. at 54.

¹⁰ 84 Fed. Reg. at 56-57.

¹¹ 437 U.S. 584, 585 (1978) ($B_1 = B_0 (1.0 - F) + PVL(F)$).

¹² See, e.g., *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1348-49 (Fed. Cir. 2017) (determining that the claims to a particular configuration of inertial sensors and a particular method of using the raw data from the sensors in order to more accurately calculate the position and orientation of an object on a moving platform did not merely recite “the abstract idea of using ‘mathematical equations for determining the relative position of a moving object to a moving reference frame’.”).

¹³ See, e.g., Example 38 (Simulating an Analog Audio Mixer) and Example 39 (Method for Training a Neural Network for Facial Detection).

¹⁴ 450 U.S. 175, 177 n. 2, 179 n.5, 191-92 (1981) ($\ln v = CZ + x$).

¹⁵ 409 U.S. 63, 65 (1972) (describing the conversion between binary-coded decimal and pure binary numerals as a “mathematical problem[] of converting one form of numerical representation to another.”).

¹⁶ 306 U.S. 86, 91 (1939). In *Mackay Radio*, while the litigated claims 15 and 16 of U.S. Patent No. 1,974,387 expressed this mathematical relationship using a formula that described the angle between the conductors ($50.9(l/\lambda < 0.513 >)$), other claims in the patent (e.g., claim 1) expressed the mathematical relationship in other ways. See also *Digitech Image Techs., LLC v. Electronics for Imaging, Inc.*, 758 F.3d 1344, 1350 (Fed. Cir. 2014). In *Digitech*, the claims at issue, namely claims 10-15, recited generating first and second data by taking existing information, manipulating the data using mathematical formulas, and organizing this information into a new form. The court explained that such claims describe a process of organizing information and manipulating information through mathematical correlations, which is considered to be a mathematical relationship.

¹⁷ See note 14, *supra*.

¹⁸ See note 11, *supra*.

¹⁹ 561 U.S. 593, 599 (2010) (Fixed Bill Price = $F_i + [(C_i + T_i + LD_i) \times (\alpha + \beta E(W_i))]$). See also MPEP 2106.04(a)(2)(IV)(A) for additional examples of mathematical equations or formulas.

²⁰ 898 F.3d 1161, 1163-65 (Fed. Cir. 2018), *modifying SAP Am., Inc. v. InvestPic, LLC*, 890 F.3d 1016 (Fed. Cir. 2018). The court in *SAP* characterized the claims as being directed to the abstract idea of “selecting certain information, analyzing it using mathematical techniques, and reporting or displaying the results of the analysis.” 898 F.3d at 1167. While there is no enumerated grouping that encompasses data analysis and display *per se* in the 2019 PEG, claims containing this type of limitation may still recite an abstract idea under the 2019 PEG. For example, the claims in *SAP* may be considered to fall within the mathematical concepts grouping or the certain methods of organizing human activity grouping. *Id.* at 1163 & 1168 (citation omitted) (describing the claims as “a series of mathematical calculations based on selected information and the presentation of the results of those calculations in the plot of a probability distribution function” or having information of an “‘investment’ character” that “simply invokes a separate category of abstract ideas involved in *Alice* and many of our cases – ‘the creation and manipulation of legal obligations such as contracts, involved in fundamental economic practices’”).

²¹ See note 11, *supra*.

²² 741 F. App’x 777, 780 (Fed. Cir. 2018) (non-precedential). See also MPEP 2106.04(a)(2)(IV)(B) for additional examples of mathematical calculations.

²³ *In re Marco Guldenaar Holding B.V.*, 911 F.3d 1157, 1160-61 (Fed. Cir. 2018).

²⁴ See, e.g., *In re Smith*, 815 F.3d 816, 818-19 (Fed. Cir. 2016) (describing a new set of rules for conducting a wagering game as a “fundamental economic practice”); *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1364 (Fed. Cir. 2015) (a new method of price optimization was found to be a fundamental economic concept); *In re Greenstein*, 774 F. App’x 661, 664 (Fed. Cir. 2019) (non-precedential) (claims to a new method of allocating returns to different investors in an investment fund was a fundamental economic concept).

²⁵ See, e.g., *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 219-20 (2014) (describing the concept of intermediated settlement, like the risk hedging in *Bilski*, to be a “fundamental economic practice long prevalent in our system of commerce” and also as “a building block of the modern economy”) (citation omitted); *Bilski v. Kappos*, 561 U.S. 593, 611 (2010) (claims to the concept of hedging are a “fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class.”) (citation omitted); *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1313 (2016) (“The category of abstract ideas embraces ‘fundamental economic practice[s] long prevalent in our system of commerce,’ ... including ‘longstanding commercial practice[s]’”).

²⁶ 876 F.3d 1372, 1378-79 (Fed. Cir. 2017).

²⁷ 873 F.3d 905, 911 (Fed. Cir. 2017). The court in *Secured Mail* characterized the claims as being directed to the abstract idea of “using a marking affixed to the outside of a mail object to communicate information about the mail object.” 873 F.3d at 911. While there is no enumerated grouping that encompasses tracking or organizing information *per se* in the 2019 PEG, claims containing this type of limitation may still recite an abstract idea under the 2019 PEG. For example, the claims in *Secured Mail* are considered to fall within the certain methods of organizing human activity grouping as a fundamental economic practice.

²⁸ 921 F.3d 1084, 1092 (Fed. Cir. 2019).

²⁹ 765 F.3d 1350, 1355 (Fed. Cir. 2014).

³⁰ 728 F.3d 1336, 1338-39 (Fed. Cir. 2013).

³¹ 671 F.3d 1317, 1322 (Fed. Cir. 2012).

³² 554 F.3d 967, 981 (Fed. Cir. 2009).

³³ 772 F.3d 709, 714-15 (Fed. Cir. 2014).

³⁴ 788 F.3d 1359, 1362-63 (Fed. Cir. 2015).

³⁵ 558 F.3d 1359, 1361 (Fed. Cir. 2009).

³⁶ 859 F.3d 1044, 1054 (Fed. Cir. 2017).

³⁷ 674 F.3d 1315, 1331 (Fed. Cir. 2012).

³⁸ 911 F.3d 1157, 1161 (Fed. Cir. 2018).

³⁹ 887 F.3d 1376 (Fed. Cir. 2018).

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⁴⁰ 645 F. App'x 1014, 1015-16 (Fed. Cir. 2016) (non-precedential).

⁴¹ 561 U.S. 593, 595 (2010).

⁴² See, e.g., 84 Fed. Reg. 52 n. 14, which cited the following cases in which the courts identified product claims as reciting “mental process”-type abstract ideas: *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307 (Fed. Cir. 2016) (product claim to “post office”); *Mortgage Grader, Inc. v. First Choice Loan Servs. Inc.*, 811 F.3d 1314 (Fed. Cir. 2016) (product claim to a computer system); *Versata Dev. Grp. v. SAP Am., Inc.*, 793 F.3d 1306 (Fed. Cir. 2015) (product claims to computer systems and computer-readable media); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366 (Fed. Cir. 2011) (product claim to computer-readable medium).

⁴³ See 84 Fed. Reg. at 52 n.14. See also *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1304 (Fed. Cir. 2019); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1375, 1376 (Fed. Cir. 2011) (explaining that the claims in *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859 (Fed. Cir. 2010), and *SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319 (Fed. Cir. 2010), are directed to inventions that “could not, as a practical matter, be performed entirely in a human’s mind”).

⁴⁴ 601 F.3d 1319, 1331-33 (Fed. Cir. 2010).

⁴⁵ 930 F.3d 1295, 1304 (Fed. Cir. 2019).

⁴⁶ 839 F.3d 1138, 1148 (Fed. Cir. 2016) (distinguishing *TQP Development, LLC v. Intuit Inc.*, 2014 WL 651935 (E.D. Tex. Feb. 19, 2014)).

⁴⁷ 627 F.3d 859, 868 (Fed. Cir. 2010).

⁴⁸ 830 F.3d 1350, 1356 (Fed. Cir. 2016).

⁴⁹ 774 F.3d 755, 763 (Fed. Cir. 2014).

⁵⁰ 659 F.3d 1057, 1067 (Fed. Cir. 2011).

⁵¹ 645 F. App'x 1014, 1016-17 (Fed. Cir. 2016) (non-precedential).

⁵² The Supreme Court recognized this in *Gottschalk v. Benson*, 409 U.S. 63 (1972), determining that a mathematical algorithm for converting binary coded decimal to pure binary within a computer’s shift register was patent ineligible subject matter. The court concluded that the algorithm could be performed purely mentally even though the claimed procedures “can be carried out in existing computers long in use, no new machinery being necessary.” *Id* at 67.

⁵³ See 84 Fed. Reg. at 52 n. 14.

⁵⁴ 887 F.3d 1376, 1385 (Fed. Cir. 2018). See also, e.g., *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1316-18 (Fed. Cir. 2016) (relying upon the specification, the Federal Circuit explained that the claimed electronic post office, which recited limitations describing how the system would receive, screen and distribute e-mail on a computer network, was analogous to how a person decides whether to read or dispose of a particular piece of mail and that “with the exception of generic computer-implemented steps, there is nothing in the claims themselves that foreclose them from being performed by a human, mentally or with pen and paper”).

⁵⁵ See, e.g., *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350, 1356 (Fed. Cir. 2016); *FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1095 (Fed. Cir. 2016); *Mortgage Grader, Inc. v. First Choice Loan Servs. Inc.*, 811 F.3d 1314, 1318, 1324 (Fed. Cir. 2016); *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1314-15 (Fed. Cir. 2016); *Versata Dev. Group Inc. v. SAP America, Inc.*, 793 F.3d 1306 (Fed. Cir. 2015); *Content Extraction and Transmission LLC v. Wells Fargo Bank*, 776 F.3d 1343, 1345, 1347 (Fed. Cir. 2014).

⁵⁶ 811 F.3d 1314, 1318, 1324 (Fed. Cir. 2016).

⁵⁷ See *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1149 (Fed. Cir. 2016); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1372-73 (Fed. Cir. 2011).

⁵⁸ The use of pen and paper to help perform a mental step simply accounts for variations in memory capacity from one person to another and should not be used to expand the scope of the mental processes grouping.

⁵⁹ 654 F.3d 1366, 1372-73 (Fed. Cir. 2011). See also *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1149 (Fed. Cir. 2016) (citing *TQP Development, LLC v. Intuit Inc.*, 2014 WL 651935 (E.D. Tex. Feb. 19, 2014)) (the specific data encryption method “could not conceivably be performed in the human mind or with pencil and paper”).

⁶⁰ *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1372, 1375-76 (Fed. Cir. 2011) (distinguishing *Research Corp. Techs. v. Microsoft Corp.*, 627 F.3d 859 (Fed. Cir. 2010), and *SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319 (Fed. Cir. 2010)).

⁶¹ See MPEP 713.

⁶² 84 Fed. Reg. at 53.

⁶³ 84 Fed. Reg. at 54.

⁶⁴ 84 Fed. Reg. at 53.

⁶⁵ See MPEP 2106.05(b), 2106.05(c), and 2106.05(f).

⁶⁶ 930 F.3d 1295, 1303 (Fed. Cir. 2019).

⁶⁷ 573 U.S. 208, 226 (2014).

⁶⁸ 827 F.3d 1341, 1348 (Fed. Cir. 2016).

⁶⁹ 827 F.3d 1341, 1350 (Fed. Cir. 2016).

⁷⁰ See MPEP 2106.05(a).

⁷¹ 827 F.3d 1042, 1048 (Fed. Cir. 2016).

⁷² 921 F.3d 1084, 1093-94 (Fed. Cir. 2019).

⁷³ See MPEP 2106.05(a)(II) (discussing *Diamond v. Diehr*, 450 U.S. 175, 187 and 191-92 (1981)) and the *Finjan* Memorandum, discussing *Finjan, Inc. v. Blue Coat Sys., Inc.*, 879 F.3d 1299, 1303-04 (Fed. Cir. 2018). The *Finjan* Memorandum of April 2, 2018 is entitled "Recent Subject Matter Eligibility Decisions", and is available at <https://www.uspto.gov/sites/default/files/documents/memo-recent-sme-ctdec-20180402.PDF>.

⁷⁴ See, e.g., MPEP 716.09 on 37 C.F.R. § 1.132 practice with respect to rejections under 35 U.S.C. § 112(a).

⁷⁵ USPTO Memorandum of June 7, 2018, "Recent Subject Matter Eligibility Decision: *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*," available at <https://www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.PDF>.

⁷⁶ 659 F.3d 1057, 1066-67 (Fed. Cir. 2011).

⁷⁷ 35 U.S.C. § 132(a).

⁷⁸ As discussed in MPEP 2106.07, claims should not be grouped together in a common rejection unless that rejection is equally applicable to all claims in the group.

⁷⁹ There has been no change in "Step 1" rejections based on a failure to claim an invention that falls within the statutory categories of invention (i.e., the claim is not to a process, machine, manufacture, or composition of matter and is thus rejected at Step 1 of the eligibility analysis). See MPEP 706.03(a) for information on making this type of rejection.

⁸⁰ See MPEP 2106.07(a)(III).

⁸¹ See MPEP 2106.07(a).

⁸² Explanation of Step 2B in a rejection written after the 2019 PEG will likely be shorter than in the past because many of the considerations evaluated in revised Step 2A overlap with Step 2B and thus, are not reevaluated in Step 2B. The exception is when an examiner had concluded, in Step 2A Prong Two, that an additional element was insignificant extra-resolution activity, in which case the examiner should re-evaluate, in Step 2B, whether the element is unconventional (i.e., more than what is well-understood, routine, conventional activity) in the field.

⁸³ USPTO Memorandum of April 19, 2018, "Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (*Berkheimer v. HP, Inc.*)", available at <https://www.uspto.gov/sites/default/files/documents/memo-berkheimer-20180419.PDF>. If the examiner relies on the finding of well-understood, routine, conventional activity to support a determination that a limitation(s) is extra-resolution activity, the examiner needs to comply with the *Berkheimer* Memorandum. 84 Fed. Reg. at 56.

⁸⁴ USPTO Memorandum of April 2, 2018, "Recent Subject Matter Eligibility Decisions", available at <https://www.uspto.gov/sites/default/files/documents/memo-recent-sme-ctdec-20180402.PDF>.

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⁸⁵ The 2019 PEG supersedes MPEP section 2106.04(II) (Eligibility Step 2A: Whether a Claim Is Directed to a Judicial Exception) to the extent the MPEP equates claims “reciting” a judicial exception with claims “directed to” a judicial exception. The USPTO has provided a chart that discusses the sections of the MPEP that are affected by the 2019 PEG. In addition, the *Berkheimer* Memorandum revised the procedures set forth in MPEP § 2106.07(a) (Formulating a Rejection For Lack of Subject Matter Eligibility) and MPEP § 2106.07(b) (Evaluating Applicant's Response).

⁸⁶ The 2019 PEG supersedes the *Vanda* Memorandum (*See* note 75, *supra*). The guidance in the *Vanda* Memorandum has been incorporated into the 2019 PEG.

⁸⁷ 84 Fed. Reg. at 51.